EA-87-02

Ontario

ENVIRONMENTAL ASSESSMENT BOARD

VOLUME: 121

DATE: Thursday, August 10th, 1989

BEFORE: M.I. JEFFERY, Q.C., Chairman
E. MARTEL, Member
A. KOVEN, Member

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EA-87-02

HEARING ON THE PROPOSAL BY THE MINISTRY OF NATURAL RESOURCES FOR A CLASS ENVIRONMENTAL ASSESSMENT FOR TIMBER MANAGEMENT ON CROWN LANDS IN ONTARIO

IN THE MATTER of the Environmental Assessment Act, R.S.O. 1980, c.140;

- and -

IN THE MATTER of the Class Environmental Assessment for Timber Management on Crown Lands in Ontario;

- and -

IN THE MATTER OF a Notice by the Honourable Jim Bradley, Minister of the Environment, requiring the Environmental Assessment Board to hold a hearing with respect to a Class Environmental Assessment (No. NR-AA-30) of an undertaking by the Ministry of Natural Resources for the activity of timber management on Crown Lands in Ontario.

Hearing held at the Ramada Prince Arthur Hotel, 17 North Cumberland St., Thunder Bay, Ontario, on Thursday, August 10th, 1989, commencing at 9:00 a.m.

VOLUME 121

BEFORE:

MR. MICHAEL I. JEFFERY, Q.C.	Chairman
MR. ELIE MARTEL	Member
MRS. ANNE KOVEN	Member

A P P E A R A N C E S

MR. V. FREIDIN, Q.C.) MS. C. BLASTORAH) MS. K. MURPHY) MS. Y. HERSCHER)	MINISTRY OF NATURAL RESOURCES
MR. B. CAMPBELL) MS. J. SEABORN)	MINISTRY OF ENVIRONMENT
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MR. H. TURKSTRA	ENVIRONMENTAL ASSESSMENT BOARD
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MR. D. HUNTER	NISHNAWBE-ASKI NATION and WINDIGO TRIBAL COUNCIL
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MR. Y. GERVAIS) MR. R. BARNES)	ONTARIO TRAPPERS ASSOCIATION
MR. R. EDWARDS) MR. B. McKERCHER)	NORTHERN ONTARIO TOURIST OUTFITTERS ASSOCIATION

APPEARANCES: (Cont'd)

MR. R.L. AXFORD	CANADIAN ASSOCIATION OF SINGLE INDUSTRY TOWNS
MR. M.O. EDWARDS	FORT FRANCES CHAMBER OF COMMERCE
MR. P.D. McCUTCHEON	GEORGE NIXON
MR. C. BRUNETTA	NORTHWESTERN ONTARIO TOURISM ASSOCIATION

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---Upon commencing at 9:10 a.m.

THE CHAIRMAN: Good morning. Please be seated.

PETER KINGSBURY,
LEONARD RITTER, Resumed

MS. MURPHY: Just a little bit of business left over from last day. If you will recall, Dr. Ritter at the end of the day, in response to a question, drew an overhead and we thought perhaps it would be wise to mark that as an exhibit.

I would suggest that you identify it as a hand-drawn diagram by Dr. Ritter and perhaps he can advise us what the title of that diagram should be.

DR. RITTER: I would just call it dose response relationship.

MS. MURPHY: Dose response relationship.

THE CHAIRMAN: Very well. That will be Exhibit 713.

MS. MURPHY: (handed)

THE CHAIRMAN: Thank you.

---EXHIBIT NO. 713: Hand-drawn diagram by Dr. Ritter entitled: Dose Response Relationship.

MS. MURPHY: And then for the evidence of Mr. Kingsbury, which we are about to commence, you will need the documents that were marked as Exhibit 711 which were his overheads; Exhibit 712, which was the

paper: Pesticides in Forestry and Agriculture; and you will also need Exhibit 604C which is the ESSA document.

MS. MURPHY: Fine.

CONTINUED DIRECT EXAMINATION BY MS. MURPHY:

Q. So, Mr. Kingsbury, perhaps you will just commence by explaining to us what the main points are that you intend to make?

MR. KINGSBURY: A. Right. Thank you, Ms. Murphy. I would like to just briefly run through the points I hope to make for the Board in this presentation.

The first one is I would like to hopefully complement what Dr. Ritter talked to you about in terms of the federal registration process and that will be my starting point, and I will be talking about how, within the area of environment, environmental effects, the federal registration process requires submission and review of data about effects on components of forest eco-system somewhat comparable to the data submission and review requirements that Dr. Ritter pointed out to you with respect to human health.

The second point I would like to make is that the use of restricted class products, which includes most of the forestry registrations, is again reviewed at a project-specific basis -- on a

project-specific basis at the provincial level; i.e., these materials are federally approved and also go through a provincial review process; federally registered, provincially approved.

Thirdly, I would like to make the point that monitoring and research of the environmental effects of forestry pesticides has been extensive and has been ongoing.

I would then like to spend quite a bit of time going through the specific area of how do we assess the environmental effects of pesticides, and I would like to spell out some of the general principles; firstly, that pesticide effects can either be direct or indirect; secondly, that direct effects are determined by toxicity and exposure; thirdly, that indirect effects are determined by the degree of dependence of an organism on aspects of the environment that might be modified through the use of the pesticides.

Having spent some time on those principles, I would then like to indicate the specific strategy that's been utilized in the assessment of environmental effects of forestry pesticides and; that is, that the impact assessments are primarily conducted on selected critical paramaters for sensitive portions of the eco-system.

And, finally, I would like to basically summarize much of the information that is in the ESSA document in a rather brief overview, talking about specific impacts on specific components of forest environments and, hopefully, lead you to a conclusion that the pesticides that are registered for use in forest management have, in fact, negligible or limited impact on the critical aspects of sensitive, non-target organism communities.

As I mentioned, I would like to begin by going back to the registration process, the federal registration process. And I'm going to go back to the same slide that Dr. Ritter utilized in outlining this process to you. I don't -- here we go.

MS. MURPHY: That's Exhibit 709, Mr. Chairman, the first page, so it would be Exhibit 709A.

MR. KINGSBURY: This figure is also within the statement of evidence for Panel 12 and I will be making some reference to portions of that statement of evidence that talk about the registration process and data requirements.

Dr. Ritter has talked about primarily Health and Welfare and the role that they play, the types of data that they review, and he has told you they do this on the request of Agriculture Canada who

are the people to whom the registration petitions are submitted and are the people who the comments then go back and who make the final decision on the registration process.

The other agencies that are involved, and I will run through them briefly, also review specific portions of the registration petition and the portions that I'm going to be talking about are the portions on environmental fate and environmental toxicology.

Basically these deal with the fate of the material once it is introduced into the environment and, of course, here we are dealing specifically with forest environment, and then the toxic effects it has in that environment.

These packages - and, in some cases, more than these packages but I am dealing with these packages in particular - are reviewed by the agencies that you see here. First of all, within Department of the Environment or Environment Canada, the Canadian Wildlife Service review this package and they, of course, are primarily interested in terms of effects on migratory song birds. They also have a broader range of interests that expand to other wildlife species as well.

The Environmental Protection Service

reviews the package with a broad range of interests in the area of environment. Some of the areas that tend to fall within their interest are, in particular, the fate of pesticides, some things that are outside the scope of what I will be talking about today such as disposal of containers and things like that.

Fisheries and Oceans Canada review it and naturally they are primarily looking at effects in the aquatic environment and the effects on fish.

Agriculture Canada has some capabilities within this area, they do review the package. Their own internal capabilities tend to be in the area of soil sciences, as you might expect, and we do receive some feedback and comment from them and certainly talk to individuals within their organization that have that expertise.

At the far end here you will see forestry and specifically the Forest Pest Management Institute. This was the institute for which I worked throughout my 15-year career and the Forest Pest Management Institute reviews -- are requested to review by Agriculture Canada the environmental fate, the environmental effects packages, as well as being the prime agency that's looking at the efficacy of the product.

As Dr. Ritter spelled out, in Canada we

in fact require that when a registration petition is submitted it also demonstrate effectiveness for the use required and Forest Pest Management is actively involved in reviewing on that aspect.

THE CHAIRMAN: Mr. Kingsbury, is the forestry section independent of Environment Canada; is it a completely independent agency?

MR. KINGSBURY: At the moment it is a separate federal department, but throughout its history it has had a variety of relationships. When I began it was part of Environment Canada, after that it was moved out of Environment Canada and was included in Agriculture Canada and just recently it has become a separate federal department.

One of the things that is peculiar about the role of the Forest Pest Management Institute, tends to be somewhat different than all of the other agencies, although not exclusively so, is that partly for some of the reasons you've heard from Dr. Campbell, et cetera, about forestry being a rather limited market and the data requirements in forestry being a particularly sensitive area and rather expensive area to work in.

The Forest Pest Management Institute as part of its mandate to provide effective and

environmentally safe tools to the forest manager gets actively involved in the generation of data. It does this primarily in the fields of efficacy, environmental fate and environmental toxicology.

One of the reasons it does this is that the Forest Pest Management itself has submitted to the registration process applications for registrations of biological materials of which it is basically the manufacturer, if I can use that term, and this of course applies to viruses.

The Institute has submitted registration packages and has received registration for viruses for forestry use and, in that role, it has to fulfill all the requirements that would be placed on any other registrant such as a chemical company.

So we have that in-house capability partly because we need it for our own products, if you can call it that, but we also get actively involved in generating data on products that come from the agro-chemical industry, come from the pharmaceutical industry in terms of BT products.

So we are both involved as a review agency in looking at these registration petitions and we are also actively involved in generating some of the data within those areas.

Okay. What kind of data is required in the area of environmental effects for these agencies to review? There is a specific requirement not only for the kind of laboratory studies that Dr. Ritter talked about in some detail on various organisms such as fish and birds and mammals, but there is a specific requirement within the Canadian registration process for studies carried out under field conditions, under appropriate Canadian use situations where the intended use pattern will come into play, and that the data generated in those conditions be done following direct application with the maximum label rate for which registration is being looked.

I would like to emphasize a couple of points with respect to this, and I will be talking about those field studies in some detail later.

First of all, the Canadian context is important. We have not registered products in Canada in the absence of Canadian field studies. We simply feel it is essential that the studies be done under Canadian conditions; i.e., Canadian forestry sites, Canadian species, species that are utilizing them which may be unique to Canada.

Secondly, I would like to emphasize that these field studies are done on the commercial product,

so they are done on the formulated material that an agency such as OMNR will eventually end up using if the material in fact is registered. That means that it includes all the components of that as the manufacturer sells it to the user.

And, thirdly, what I would like to do is -- or what I would like to emphasize is that if the product is to be used in forestry situations in Canada by any kind of application method that involves disseminating it fairly broadly - i.e., this is exclusive of something such as a tree injection type of situation that Dr. Campbell talked about where it is actually injected right into a tree - if it is going to be broadcast from ground or aerial sprayers, there is a requirement, the data on its fate and effects and aquatic systems be carried out utilizing direct application to flowing and static waters. What this means is that we have to test it flying an aircraft directly over an aquatic system.

Now, this is done recognizing that this in fact is not the common practice in forestry operations, that we utilize things such as buffer zones to get away from that kind of exposure. However, we simply feel that the expansion of the use of a product from something like soyabeans or corn into forestry

provides the opportunity for expansion of the exposure to aquatic systems. And I think you will recognize here some parallels with what Dr. Ritter was saying regarding when you expand the use you look at what is the expansion of the potential exposure and risk involved with that use.

It's important to keep this in mind that when I talk about aquatic effects I'm talking about aquatic effects measured under direct overspray. That's what the registration process considers.

Okay, moving on to my second point. When Agriculture Canada register products they assign them to product classes and --

MS. MURPHY: Q. I'm sorry, just before you go on--

MR. KINGSBURY: A. Sorry.

Q. --perhaps just for the record we should point out that the list of all of the different kinds of data that's required is in Dr. Ritter's paper.

And just for the record and for your information, the entire list with some description is on page 87 to 88 of the statement of the evidence for Panel 12, Volume I.

A. And the specific areas of environmental chemistry and environmental toxicology

are Items F and G on page 88.

Q. Sorry to interrupt.

A. That's okay. I was talking about the restricted class. The restricted classification for products to be used in forest management ensures that further project-specific review will be carried out at the provincial level.

Why are forestry products put into this restricted classification? I would refer you to and will quote to you from page 96 of the volume of evidence, and basically it says:

> "This designation reflects the historical perception that both the aquatic and forestry environments, being in a natural state, are more environmentally sensitive and, thus, warrant particular care and attention."

Q. And that's from that same volume and also from Dr. Ritter's paper; is that right?

A. That's correct. I would emphasize that it is not related to the nature of the product itself, although in other situations; that is, where the use of the restricted category could come into play.

For instance, with a material that might

be used in fumigation within homes it might be restricted and the restriction might be that it had to be applied by a licensed applicator.

In this case it is not related to the nature of the product and its inherent toxicity, and that can be demonstrated by the fact that rather innocuous materials such as viruses and bacteria, BT in specific, are classified as restricted products just as broad spectrum chemicals used in forestry are.

The practical ramification of this classification of these products into the restricted category is that the appropriate provincial body must provide specific permit for each aerial application for forestry of the pesticides that are in this category.

In Ontario, this permit -- permitting of of course is done by the Ministry of the Environment. What it means is that there is an examination of the project, a requirement to submit maps, project descriptions, things like that to MOE and the opportunity for MOE to impose appropriate conditions on that application and generally this involves the application of buffer zone restrictions to the project.

Now, Mr. Nicholson and Iskra have gone into some of the details of how this actually comes to play at the project-specific site level.

Okay. The third point I would like to make is that this is not the end of the evaluation process in that post-registration monitoring and research studies for forestry pesticides has been extensive and ongoing and has resulted in feedback into and continuation of the evaluation process.

It is a fact that in forestry a great deal of research and monitoring effort has been carried out after the product has been registered. That's not to imply that we haven't gone through the steps I have described prior to registration.

What are the reasons for that? Well, first of all, it reflects the climate in which these products came into play. I am talking now about the products we are dealing with in this process, the Ministry's proposing to use, and these are basically the products that have come into play primarily in the 70s. And, as we know, that was an area when, one, there was a lot of growing environmental awareness, there was a great deal of environmental legislation being put into place in different jurisdictions. This also coincided with a very expanded -- great expansion of the spruce budworm infestation and with spray programs attempting to deal with that.

During that period there were a lot of

new jurisdictions getting involved in new uses and use patterns and strategies of using these materials, although they continued to use the same registered products. And in the process of those new strategies coming into play and large scale operations, a lot of research and monitoring was done.

The Forest Pest Management Institute itself did a great deal of this, but there were also a lot of other agencies involved. In fact, in many jurisdictions for a period of time when they had large operations, there were very active environmental monitoring committees in place whose members did a lot of studies.

Some of the new use patterns or strategies that were looked at at this time were applying the material to earlier stages of the budworm than had been normally the case, what we call L2 spraying, spraying second instar larva, trying to knock back at a very early stage in its development infestations that were at a very, very high level.

Another strategy in which a fair bit of spraying, largely at a research level, was done was using these materials to try and reduce moth populations, spraying adult budworm. And then there were also things like the introduction of four-engine

aircraft into situations like Maine and Quebec and the recognition that this required doing environmental studies because of an increased potential for introducing the material into small lakes as a for instance.

So there was a lot of additional post-registration work done particularly on budworm insecticides, but the same interests tended to result in work being done with other pesticide uses.

These research and monitoring programs involve federal and provincial agencies and universities, and a lot of the data that was generated at that time still serves as very important data in the data package. Much of that information you will in fact find within the ESSA Document.

As this data was generated it was fed back into the registration process and it now forms part of the data package that sits there.

Now, much of this data was not specific data that generated by a registrant; for example, everything the Forest Pest Management Institute does is basically public data, but it is also taken by the manufacturer of the specific product and submitted as part of the support for their registration package. We, of course, send the data directly to all of the

bodies that you see involved in the registration process so that they have it there and available.

I would like to basically shift gears now and start to talk about pesticide impacts in the forest environment. And one of the things I would like to suggest, and certainly that is very much reinforced to me by my experiences, is that although we are dealing with a complex issue, there is much about pesticide effects that is in fact common sense and predictable. It's possible to look at some general principles and to, I think, get a fair grasp and understanding of the assessment procedures that are used.

The first point I would make is that pesticide effects are either direct, and by that I mean they result from the toxicity, the direct toxicity of the pesticide to the organism that is affected; or they can be indirect, and by that what I mean is they are due to the organism being affected by the pesticide's direct effects on other organisms or on their habitat.

I will give you a simple example of the difference between direct and indirect effects and I will talk about a caterpillar, for instance. A caterpillar could be affected by an insecticide by being directly poisoned by the insecticide, in fact that is the intent of insecticides, so that is a direct

toxic effect.

A herbicide on the other hand might -- is most likely to affect a caterpillar by affecting the plant material that the caterpillar would eat. Now, that may have the same eventual consequence in terms of the caterpillar, the caterpillar may die because it's food source dies, but it would have been an indirect effect of the herbicide.

Just expanding this I would like to present the same kind of thing with respect to say a song bird, a forest song bird.

An insecticide might exert a toxic effect on the bird. Now, it's less likely that the insecticide would affect the bird because, of course, it's been selected for its activity on insects not on birds, but it may still have a toxic effect on the song bird.

On the other hand, the insecticide might affect the song bird indirectly by changing the behaviour of its insect prey. For example, if it knocked a lot of budworms out of trees it might make them much more available to the bird on the ground. That would be an indirect effect. It might be perceived to be a positive effect making a food supply available. Or that same effect could become a negative

effect, indirect effect, if in fact a large portion of the song bird's food supply was removed because of the direct toxic effects on the food supply.

You can also have indirect effects through habitat of both insecticides and herbicides. For example, a bird could be indirectly affected by an insecticide if the insecticide preserves the foliage on a tree where it's nest site is. It may in fact enhance its ability for reproductive success by maintaining the integrity of its nesting site. And, as you can tell, I have given some intentional positive and negative indications of indirect effects.

It is hard to think of positive direct effects, positive effects that come because of the toxic response. Indirect effects need to be evaluated thinking of -- in a broader scope of, they can be positive, they can be negative, they can be neutral.

THE CHAIRMAN: Can you not view a positive net effect by eliminating a pest that in turn is very detrimental to a particular species?

MR. KINGSBURY: Yes, and that would be an indirect effect. Although it's because of the direct toxicity on the pest, it's an indirect effect on the species we are talking about.

Okay. And maybe we should pursue that a

little bit more. As I said, a herbicide -- there is little likelihood of a direct toxic effect on a song bird, the product has been developed to affect plants. Okay. The impact on the song bird would be indirect through the ways in which the herbicide alters the plant community both in the short term and the long term and, again, these indirect effects could be positive or negative. And I think Mr. Buss pointed out that this depends on the specific habitat requirements of the individual species and that over the duration of, say, that herbicide's effects on the plant community in the short term it might be negative to one species, positive -- in the long term positive to that same species, or vice versa.

Another thing that is very important to take into mind are: What are the habitat values present on the treated site before the treatment. We have to recognize that herbicides are used in areas that have previously between harvested. They tend to be areas that provide little habitat for most song bird species.

And I think it's a fair assumption to say that the effects of herbicides on most song bird species are primarily going to be effects seen 3, 5, 15 or 50 years down the road simply because at the time

the herbicide is applied to the site, the site does not provide a great deal of habitat for most song bird species; it certainly doesn't provide any habitat to speak of for song bird species adapted to mature conifer forests.

Now, if in the long run the use of that herbicide converts land back into mature conifer forests faster or converts lands that wouldn't go back to mature conifer forest, then down the road there may be a net positive effect for that species.

For other species, the birds that are adapted to a mixed woods forest or to a heavy shrub layer, the herbicide may tend to have a negative effect of removing habitat faster from the system than might be the case if you didn't spray it.

The important thing is to consider the habitat value of the treated stand as compared to the stand that would have existed without the herbicide intervention. And, of course, another thing that becomes important here is in terms of the magnitude of the potential effect on any species are considerations such as: What is the size of the treated area, what is the proximity of it to other habitat available, and this is just as true for a herbicide application as it is for any other silvicultural procedure that is

changing the qualities of the habitat within a given area.

Okay. I would like to move now to consideration of direct effects. Direct effects are primarily determined by the toxilogical properites of the pesticide, that is the first factor; and secondly, by the nature and the duration of the organism's exposure to that pesticide, both nature and duration, and I will be talking about those.

Briefly in terms of toxicology all I'm going to say is that in general there are some very general common sense things come into play.

Insecticides are mostly toxic to insects and related creatures like spiders, they have lesser -- tend to have lesser toxicity to higher organisms such as fish, birds, mammals. They tend to be very -- of very low toxicity to plants. Herbicides are primarily toxic to plants and generally have very little toxicity to other organisms.

Now, toxicity can vary via route of exposure and Dr. Ritter went to some length on various routes of exposure that are evaluated in terms of human health considerations. Oral, you know, via the diet; contact via contact with surfaces. The same thing comes into play in terms of direct effects on other

organisms. This leads us to a consideration of basically the fate, the fate of these pesticides when they end up in the environment. And I will be addressing this from the perspective of their fate, of course, determines the exposure of organisms to them. Okay.

I'm going to do this fairly briefly. There is considerable discussion of this and evidence for it in the ESSA Document describing levels, pathways, et cetera.

I would just note for you, but I don't intend to discuss at this point, within the ESSA Document, Table 5 on page 40, and this is a very quick summary of typical maximum exposure levels, if you want to call it that, in terms of concentrations of the pesticides we are talking about that end up in various parts of the forest environment after applied.

I may use the word substrates for those parts. By a substrate I simply mean a part of the forest environment such as soil or foliage or berries. When the material is applied to a forest site it ends up in or on these various substrates.

Now, there is an important distinction there in terms of whether it's simply on or whether it has moved into, and I don't intend to go into a great

deal of detail on that, simply to point out that the material may be more or less closely associated with whatever that substrate is.

Herbicides, because of the nature of the sites that we apply them to, having been recently harvested, tend to end up in two major compartments of the environment; plants themselves which, of course, are the target or soil. Now, soil is sometimes also the target if we are applying the material as a site prep treatment.

In both of those substrates the herbicides that we are talking about tend to have half lives; i.e., times in which the initial residues decline by 50 per cent that are measured in terms of weeks.

There is all kinds of factors that influence the half life of a given material on a given site. The organic versus inorganic component within the soil as a for instance. Many of these herbicides might be very strongly bound to organic material and that might tend to make them persist for a longer time. The amount of rainfall, soil conditions, light penetration, all kinds of factors affect that and I'm not going to go into it in depth -- detail.

I mentioned that persistence in these

substrates for herbicides tends to be in the matter of half lives of weeks. One exception is simazine. Dr. Campbell spelled out the use pattern for this material. It's primarily used within southern Ontario in old field situations where you are basically taking an agricultural site and trying to convert it back to a forestry site. Simazine, unlike the other herbicides we are talking about, tends to have a half life in soils measured in terms of months.

Insecticides are primarily applied to rather mature forest sites. The first major consequence of this is that most of the insecticide ends up on foliage. In many instances we measure very little insecticide reaching soil, reaching the forest floor after the spray application and, of course, the foliage is where we want to get it because that is where it performs its function.

The insecticides that we are considering here have half lives in foliage that is measured in terms of a few days. Again, depending on many of the parameters I have talked about; amount of rain, sunlight, penetration, the nature of the foliage it lands on, et cetera, but they tend to disappear from that foliage rather quickly.

There is one exception to that in that

small amounts of insecticides, particularly the chemical insecticides, may in fact become tightly a associated with the cuticular waxes on the conifer needles' surface and that has been shown to be an area where, although most of the material on foliage disappears rather quickly, some of it that is tightly bound to that waxey surface will in fact persist for a rather long period of time, by that I'm talking about years.

Once that needle -- conifer needle falls to the forest ground and begins to break down, it appears that the material becomes just as liable to the rapid breakdown that I described before. So it's basically because it is tightly bound to the waxey surface may in fact be chemically locked up with those cuticular waxes that we can continue to measure for a long period of time. That, of, course greatly limits its biological activity, in fact those kinds of residues are very difficult for an organism to pick up.

Okay. I would like to start talking about organisms now and ask, Greg, if you can switch on the next overhead.

Q. And this is Exhibit 711, page B.

A. I have entitled this: Generalized Pathsways of Potential Insecticide Effects on an

Organism in the course of the environment and I will be going into a more specific situation in a moment. What I would like to point out here is that the pesticide which has its own particular toxicological properties can come in contact with the organism, whichever one it is we are considering, by direct contact with the spray, in terms of contact with spray droplets, or because the material has been deposited in the forest environment, and I have separated this deposition into substrates that the organism contacts. You might consider it sort of the surfaces in which it comes in contact as it goes about its activities sort of in a very impartial context like the floor you walk across, and substrates that the organism utilizes. These may be things like other organisms that it ingests or nesting material that it collects and brings back to a nest.

One of the things you will recognize, this are different toxicological pathways just as Dr. Ritter spelled them out. For example, direct contact with the spray may come through inhalation, the organisms actually breathing the spray droplets in. Contact with substrates; that is, just crawling across, of course, is a contact toxicity via through the skin, it's a dermal exposure. And, of course, contact with

things it's eating becomes an oral exposure.

So we see the same pathways of exposure are possible for an organism as they have been spelled out by Dr. Ritter. And, in fact, in the toxilogical environmental toxicology data packages these different pathways are evaluated. In general, the really important -- for an insecticide the really important pathway is this one, it's the direct contact with the spray that presents the most concentrated material exposure with the most concentrated material. And Dr. Ritter has talked about, you know, the need for a exposure to enough of the material to exert a toxic effect. This is the pathway which tends to be the most important one for an insecticide whether it's going to have a direct toxic effect.

I think this is an appropriate point to talk about the whole area of bio-accumulation, bio-concentration, bio-magnification. Basically what we are talking about here is a couple of things. What residues end up in this organism, how do those residues relate to residues that are within the environment in general, and I think this is an area that a lot of confusion can come to play and so I would ask you to think -- you know, take a look first of all within the ESSA Document, consider the way in which we have used

these terms in this document. And these definitions are spelled out on page 176 of that document.

Now, I would caution that the use of these terms in this way may not be the way in which they are referred to in ordinary conversation or in scientific papers, that there is quite a number of ways to talk about these terms. I will talk about them in the context of how the ESSA Document has used them and I hope that I will be consistent throughout this process in using them in that way. And if you need clarification at any point please ask me, because I could be as confused as you might be.

By bio-accumulation we are using that in the context of what is here without any respect, what is in the organism with no respect or regard to what is happening in the environment. And it is true that for all of these materials they can be found after use in organisms, you can find them in birds and fish and insects and that, in the context we are using the word, that is evidence of bio-accumulation; the material is there, it can be found.

Bio-concentration implies a relationship between what is in the organism and what is in the environment and, as the word sounds, it indicates a concentration in the biota, within the organism. So we

are implying an elevated level within the organism over what is in the environment.

Basically what that is implying, that bio-accumulation may -- you know, saying the material moves into organisms. Bio-concentration means its continues to move into organisms and it doesn't move out of them. Bio-magnification implies that as you go up the food chain, one organism that is feeding on other organisms that have pesticide residues in them will continue to accumulate those residues and will end up with more residue in it than the organism at the lower level.

For the pesticides that we are considering in this exercise, as I mentioned, we see bio-accumulation when -- that we can find these pesticides within organisms. There is no evidence for these pesticides of bio-concentration or bio-magnification in terms that I have spelled out to you, and I think that the best way to say that is that once exposure -- environmental exposure ceases the materials will no longer be found in the organism.

Now, there will, of course, be a clearing time, a time period that it may take for the material that has been there to disappear. With many of the materials we are talking about we are talking here in

the order of hours. They are in fact highly liable to the processes, primarily of excretion, of elimination, that most of these materials can move out of organisms almost as readily as they move into them and they are also liable to a certain extent to metabolism within the organism, that the organism can break them down.

THE CHAIRMAN: When you say, Mr. Kingsbury, that there is no evidence of bio-magnification or bio-concentration for the pesticides--

MR. KINGSBURY: Mm-hmm.

THE CHAIRMAN: --does that mean to say that that is the imperical position, or are you implying that if there was any bio-concentration or bio-magnification found you would not register the pesticide?

MR. KINGSBURY: Basically, I think what we can imply from the fact that we don't see them in these materials which are, of course, registered and being used, is that the registration process has already ensured that these things don't incur.

THE CHAIRMAN: And if it did occur, I take it you would not register it; is that correct?

MR. KINGSBURY: Yes, that's correct. And I think you can recognize that in the late 60s the

registration process and one of the things that really drove the registration process was the fact the recognition of bio-concentration and bio-magnification associated with some of the materials in use at the time and, of course, DDT is the classic, and the hazards that that presented.

And that, in fact, is something that is looked at very closely in the registration process and is perhaps one of the real red flags that would prevent registration of a product, regardless of its other qualities.

THE CHAIRMAN: And are you running these tests for bio-concentration and bio-magnification using the most conservative detection methods, like parts per quadrillion or whatever we can ascertain today, as opposed to what might have been used in the 60s and 70s?

MR. KINGSBURY: I think I could probably say with a great deal of certainty that residues are now being evaluated probably 3 to 6 orders of magnitude lower than we were capable of looking at at those times I think in the products you are talking about.

Analytical chemists are incredible people in terms of pushing their science to almost mind-boggling limits. You think of a part per billion

in terms of the human population and you recognize just how small that is. Even these -- even studies done right at the initial stages are routinely looking at tenths and hundredths of parts per billion and the technology is there to push that even further.

Okay. I would like to move on now to basically what is below the line here. And now really what we are talking about, or what I would like to talk about is what are the nature of the effects on the organism and I would like to concentrate on two very specific and important bottom line effects, if you might call it that.

There can, of course, be an effect that basically is as simple as the organism comes in contact and dies. We are, of course -- you know, we are interested in that, but I think we are more interested in what are the consequences of that. One of the major things we are interested in: Is this species capable of carrying on reproduction and producing subsequent generations.

You could kill the organism, you could make it sick or you could change its behaviour in a fashion that causes it to be incapable of reproducing. You can consider that at the individual level, you can also consider it at the population level, and we are

aware that death of individuals or the inability of individuals to reproduce doesn't necessarily mean the population will not be able to reproduce and sustain itself. And, of course, the prime example we can use here is insect infestation that is treated with insecticides and is still able to maintain an outbreak status.

That is sort of an extreme example of how you can affect a lot of individuals and not necessarily depress a population. That applies primarily to things that are capable of very rapid reproduction, like insects. To a lesser effect it is also true of things like small mammals and birds and, to an even lesser effect, of course, when you get to larger organisms. We can also impact on an ecological role or an ecological function that is associated with that organism.

Every organism contributes to ecological processes. This can be via transferring energy through an eco-system by serving as either a prey organism or as a predator on other organisms, or as a herbivore on plants. It can be by a function of helping to exert pressure on other species populations by being a predator or perhaps a parasite of that other species, so it can keep that other species population in check.

That can be considered an ecological role or function.

It can be involved in breakdown in cycling of nutrients, taking dead plant material and returning it to soil, things like that, or it can be something as specific as pollination, okay, playing the role of serving as a -- carrying pollen from one plant species to another and, therefore, be an essential link in plant reproduction.

So, again, I would like you to sort of keep in mind those two major types of effects, and you can see where we have sort of moved beyond the organism level and we are starting to get to population level.

Okay. What I would like to do now is take this generalized pathway and apply it to specific organisms. If I can have the next overhead. And for the purpose of this example, the organism I have chosen is a bee.

MS. MURPHY: Q. That's Exhibit 711, page C.

MR. KINGSBURY: A. Okay. I'm just going to briefly say a bit with respect to an insecticide and we will talk about a chemical insecticide, a broad spectrum insecticide and a bee, sort of try and draw out some of these principles I have talked about and illustrate them.

The first thing, as I have mentioned, with a bee, the bee is most likely to be affected by direct contact with the spray cloud. The consequence of that, there are a number of ways in which that -- of factors that come to play. First of all, is the bee going to be in contact with spray droplets? That may require it to be out and actively moving about the environment for the rather short period of time that the insecticide is present as spray droplets.

Our institute used to do a lot of work with honey bee colonies, taking them out into spray areas, and one of the things we quickly discovered is that very often, if an insecticide was applied under fairly typical conditions, early morning or late evening, we simply didn't get an effect on bees because they weren't out and exposed to the spray itself.

Now, that was irregardless of the fact that the material might have been highly toxic to those bees because you have got to have the exposure. We had other instances in which the material was applied on warm days, later in the day, our bees were out and actively foraging and a lot of bees were killed because they had that contact.

If you talk about wild bees and, you know, we are dealing with a complex in the forest of

perhaps somewhere in the order of 50 to 70 species of wild bees, most of which are solitary, unlike the honey bees and bumble bees which live in colonies, you have a whole range of possible scenarios in terms of where they might have their nesting sites, their resting sites, when they might be active, that kind of thing.

Again, when bees were -- honey bee colonies were out and in direct contact with the spray and we did document extensive mortality, we still, in the majority of instances, saw that the colony vigor and strength by the end of the season was quite normal compared to untreated colonies and that's because a portion of the population was within the hive or was in the egg stage or the pupal stage or the larval stage which didn't have the same exposure and which, in fact, in many instances can have a totally different level of sensitivity to a given insecticide.

Okay. One of the reasons we use bees a lot is that they are very good organisms in terms of both this and this pathway. Bees go out and they contact the air and they crawl across soil and they crawl across plants and flowers and they collect pollen, they collect nectar from plants, they collect propolis, which is sort of gum from trees that they use to stick up their hives and make it hard for the

beekeeper to get in, and they collect - wild bees in particular - nesting materials. They tend to be a rather good species for sampling the environment.

But for any organism there is always the possibility that some particular aspect of one of these pathways might become prominent all of a sudden and I would give you an example. There are some insecticides - and I am not limiting this to forestry now, I'm actually thinking more of agricultural materials - that are formulated in a fashion that they are disseminated in the environment in a certain particle size as very small particles and, in some instances, we found that bees actually collect these particles in the activity of collecting pollen. They may not actually seek them out, but the particles sitting around are simply liable to being gathered, concentrated and taken back to the hive and, in fact, can have some very negative impacts on bees.

So that's an example of sort of a place where all of a sudden because of some specific quality of the pesticide or some physical quality of the way in which is out there in the environment, a particular species suddenly gets impacted to a high degree.

I would just like to briefly then talk about this ecological function in terms of bees.

Q. Can you just tell me: Did anything happen as a result of finding out that there was this problem with the size of the particle?

A. There have in fact been products where the manufacturer has reformulated the material in a different format; for example, taking it from tiny solid particles and made it a material that's applied as a -- in solution and that has, in fact, eliminated the problem of the bee collecting it, taking it back to the hive and suffering impacts.

Okay. I've talked about how a bee colony, as a for instance, can be resilient to the loss of some of its individuals. An ecological function, such as pollination, may be even more resilient and one of the things that comes to play here is that in nature it is not very often that an ecological function is dependent on only one species.

For example, pollination of forest plants involves not only a variety of bees - and I have mentioned perhaps 50 to 70 bee species - but a whole bunch of other insects and even vertebrates that play a role in pollination; things like ants, butterflies, wasps, even hummingbirds and bats are important in pollinating of some plants.

So a pollination process might be

resilient even to the degree of being resilient to a large impact on one species. One of the ways that the resiliency can be there is because a reduction in the contribution of one species can be compensated for by an increase in the activity of another species, and I would like to get to a specific example pertinent to the topic we are talking about today.

Fenitrothion is known to be capable of impacting quite heavily on bumble bees. If bumble bees are out, and particularly if they are out foraging at the time of spray, fenitrothion can cause direct mortality of bumble bees to a fairly extensive degree.

In New Brunswick, some studies done there have shown where fenitrothion sprays that impacted heavily on one species of bumble bee that emerged early in the season reduced the populations of that type of bumble bee and potentially that, of course, would have reduced their role in the pollination process and the overall function of pollination in that eco-system. However, in this case, the researchers found that later emerging bumble bee species who emerged from their nest sites later in the season built up their populations to higher than normal levels.

Now, this was a consequence of lack of competition with the earlier emerging species. In

other words, they were able to go out and find more food and expend less energy getting that food and put more of that energy into the reproductive efforts and, therefore, built up bigger colonies and thus, to a certain extent, they compensated in terms of the overall pollinating activity in that system and the plant -- its contribution to plant reproduction.

Now, in saying that we have to recognize that there may be some specific linkages; for example, there may be a plant species that depends exclusively, for one reason or another, on that early emerging bumble bee species. So we are not saying that we haven't necessarily had a fairly critical effect on one kind of thing, but there tends to be these compensating mechanisms built into virtually all ecological functions.

Q. Okay. Mr. Kingsbury, I understand that basically up to this point you have been discussing the pathways for direct exposure in the terrestrial environment, the possible pathways.

I understand you are now going to be going on to discuss in some detail the pathways -- potential pathways for direct exposure in the aquatic environment.

And I would suggest, Mr. Chairman, if you

would like to take a break at this time it would probably be a good spot.

THE CHAIRMAN: Okay. We will break for 20 minutes. Thank you.

---Recess taken at 10:25 a.m.

---On resuming at 11:00 a.m.

THE CHAIRMAN: Thank you, ladies and gentlemen. Please be seated.

Ms. Murphy, just before we go on there is going to unfortunately have to be a slight schedule change to the hearing schedule.

We have a conflict on the Friday, August the 25th. We were going to sit Tuesday through Friday that week and what we are suggesting is, is that we come in Monday night on the 21st - we weren't going to sit the 21st either - and sit the full day on Tuesday, Wednesday and sit a full day Thursday and not leave until the 7 o'clock flight or we will sit until five or however late we have to.

In that way we will have made up most of the time that we would be losing by not sitting on the Friday.

MS. MURPHY: And we are expecting at that stage Panel 14 would probably be in cross-examination.

THE CHAIRMAN: That's right.

MS. MURPHY: Thank you.

THE CHAIRMAN: Again, you know, we try to set these schedules as far as we can in advance, but unfortunately things do come up that we have to make amendments from time to time.

Thank you.

MS. MURPHY: Unless there's any problem for anyone else, it is certainly not a problem for us, sir.

THE CHAIRMAN: So we would be commencing on the Monday -- sorry, on the Tuesday at 9:00 a.m., if that's clear to everybody.

MR. KINGSBURY: If I might just make two points of clarification. Dr. Ritter pointed out to me that, like others I have read about in the transcripts, I have been using the royal "we" a little bit.

Just to remind you, I do not make regulatory decisions or I did not make, Agriculture Canada makes the decisions, and with respect to bio-accumulation I more or less implied that I wouldn't let this happen. That of course is Agriculture Canada's role.

I have a great deal of confidence that they would in fact take the regulatory position that they spelled out and that would be the recommendation

that would come certainly from Forestry, given that I would be the person involved in making that.

And also, just to clarify whether there was some confusion again when we were talking about that, Mr. Chairman, you indicated an interest in how sensitive -- how finely can we detect these things. The point of course is with bio-concentration and bio-magnification that really that's an area where you don't need the sensitivity of residue analysis because you are looking from quantities that are building, okay.

The analogy might be, if you put pepper on your entire dinner and it's moving into your little piece of meat from everything else on there, then it is concentrating and magnifying in that portion, it's easier to detect.

Ms. Murphy indicated I'm going to move on now to talk about direct effects in the aquatic environment and, of course, I have indicated that direct effects contigent on toxicity and exposure.

I would like to first of all talk about exposure. In the course of this I am going to be making periodic reference to an article which I was a co-author and, in fact, a section of this article which I was the sole author of which you have in front of you

I believe as an exhibit.

MS. MURPHY: It is Exhibit 712.

MR. KINGSBURY: So you might just want to have that out. One thing that's unique about the aquatic environment is that, of course, all exposure comes through water, that's generally true.

The implications of that are that the more you can keep a material out of the water the more you reduce exposure to all the organisms within the water and that, of course, is one of the reasons that buffer zones can be particularly effective in aquatic situations because if you can reduce the introduction into the water you can greatly reduce exposure and the potential for effects. Nevertheless, with or without buffer zones there are ways and means by which pesticide residues can enter water.

How can they get into water? I would like to make reference now to a table on page 260 in this article and this table talks about the different pathways or entry mechanisms of pesticides into water following their use in a forestry context.

MS. MURPHY: Q. Okay. That was page 260?

MR. KINGSBURY: A. That's correct. It talks about the pathway or the entry mechanism and then

it makes some general comments on the size of the exposure through that pathway and the duration.

The first two pathways are called direct and drift, and this is relating to entry at the time of spray application either because of direct application; i.e., the application equipment passing over the aquatic system, or because of spray drift moving from a treated area into an adjacent aquatic system. In both cases, immediately after the application material will be deposited directly on the surface of the water and then disperse into that aquatic system.

So it is an entry route that is -- only happens for -- basically for the length of time that you are actually applying the material. It's for a very short period of time, usually minutes or hours. And I would suggest that these are by far and away the main routes by which the pesticides we are talking about enter aquatic systems and, in fact, it represents the highest exposure pathways.

The next two routes spelled out here are through ephermeral channels and basically what that means is the material is applied onto dry land which is flooded at a later time and through overland flow, if you have a very heavy precipitation event and you actually get water flowing across the surface of the

forest floor into an aquatic system. Overland flow might be expanded particularly in the context of insecticides as dripping out of the trees.

This, of course, pathway will depend on a number of factors. One is: How easily can the material be picked off these substrates and moved with water that is moving into aquatic systems, it will depend on the magnitude of the rain events and when they are timed in relation to your spray application, and it represents, probably in many situations, a fairly modest potential pathway, but it all depends. Certainly in coastal British Columbia we have seen where you can have a very significant rain event and this can be for a small period of time, a fairly large exposure, and I will be demonstrating that with some data in a moment.

The final pathway measured here is leaching and leaching means that the pesticide moves with water through the soil and into aquifers, into ground water or directly into an aquatic system.

THE CHAIRMAN: Mr. Kingsbury, what in general terms is the solubility of pesticides in general; are they soluble in water?

MR. KINGSBURY: It varies a great deal with the individual pesticides. Some are extremely

soluble and some are very low solubility. The pesticides we are dealing with, without having the data in front of me, I think we are probably dealing with differences of three or four orders of magnitude in their solubility in water.

Leaching, of course, can potentially lead to a long duration of exposure but at very low levels.

MS. MURPHY: Q. Does solubility have anything to do with the potential for leaching?

MR. KINGSBURY: A. It's one, but not the only factor that comes into play. As a for example, glyphosate or Roundup or Vision has a relatively high solubility in water, but it also is a material that is very tightly bound to soil particles, and these two things tend to be in conflict in terms of its ability to leach.

The bottom line is that the soil -- organic matter in the soil captures it so tightly that it shows virtually no leaching potential and field studies to that -- about that have been included in the ESSA review. And, in fact, for both the herbicides and the insecticides that we are dealing with there have been -- the studies that have been done have shown that none of them show any significant tendency to leach.

Okay. I would like to go back to those

first two exposure pathways, direct introduction and drift, and to do this I would like to draw on some data that comes from an experiment in which I was heavily involved carried out on the west coast of B.C. called the Carnation Creek experiment.

Q. And that is the experiment that is being discussed in this exhibit; is that right, Exhibit 712?

A. That is correct. In this experiment glyphosate was applied for experimental purposes to a watershed on the west coast of Vancouver Island where the Department of Fisheries and Oceans had carried out a long-term study on the effects of harvest -- forest harvesting on a small stream and the salmon populations within it. It is certainly a benchmark study, both in terms of fisheries research and fisheries forestry interactions. When we got involved the study had been running for some 16 years.

And basically what had happened, they had studied prior to harvest, over the period of harvest and following harvest fish populations, water chemistry, a lot of parameters, and as the site which had been planted came up in competing vegetation the opportunity was there to continue this study by doing a herbicide application and it gave a rather unique

opportunity to compare the types and magnitudes of effects from a specific tending operation involving a herbicide with effects that had been documented previously following logging operations.

The experiment was carried out under the experimental conditions that I discussed in the data requirements portion; i.e., a portion of this experiment dealt with looking at environmental fate and effects following direct overspray so that one small tributary to the creek was directly oversprayed. The spray aircraft - a helicopter in this case - directly overflew the stream. It just pretended it didn't exist, it was just part of the forest block.

Another portion of the study involved looking at what would happen with a -- when a buffer zone restriction was applied and, in this case, the buffer zone was a 10-metre buffer.

The first slide that I'm showing you, and this is Figure 162 on page 260A, the slide on the left side of the page -- or the figure on the left side of the page in the document before you is a measurement of the residues of glyphosate, that's the solid line, and also the main breakdown product of glyphosate, AMPA, which is the dotted line. And this is within the tributary that was directly overflown by the spray

aircraft.

You note the time scale here, talking about the first 96 hours after application and, in fact, there were no measurable residues detected following that period.

What you see is that shortly after application you see this initial high -- highest level measured in water and this is from the direct introduction of the material in the stream. The application lasted about three hours on this site and following this you see a rapid decline in the residues within the first 10, 12-hour period.

At that point there was an extremely heavy rain event, and by extremely heavy I mean that the water level within this tributary more than doubled, well more than doubled, and associated with this rain event we saw another peak in the herbicide, the glyphosate concentration within this stream and this would represent those routes of -- these pathways of entry from being washed off of foliage and water flowing over what had previously been a dry streambed and also moving over the land into it.

But, once again, after the rain event, you see a very rapid decline to low levels here.

Q. And this particular graph differs a

little bit from the one that is shown in the paper on page 260; in particular, that it shows the dotted line at the bottom AMPA.

MS. MURPHY: And, Mr. Chairman, we will be photocopying these particular slides. They are a little different from the one in the document.

MR. KINGSBURY: Yes. Basically AMPA was -- the breakdown product was only detected in very few samples at very low levels and what -- this basically then would represent the type of exposure to fish or aquatic invertebrates in that tributary. And as you can see, it's not -- it's a very dynamic thing, that the concentration in the water is constantly changing.

To try and put this in the perspective of what would be a toxic level for an organism such as a fish, if you refer to the preceding page, page 259 in the document, I have given toxicity measurements that have been evaluated in laboratory situations and I have given values for them.

Under glyphosate you will see for rainbow trout, which is in fact generally the most sensitive or as sensitive as any of the other aquatic organisms including aquatic invertebrates for which the data is presented, the values here for glyphosate technical is

130 units, that would be milligrams per litre or parts per million, okay. That number is not the number we should be looking at though, because we weren't looking at technical material. As I spelled out, these field tests are done with the commercial product as it's going to be used.

MS. MURPHY: Q. The technical material is the same thing as the active ingredient?

MR. KINGSBURY: A. The technical material is basically pure pesticide. It's trying to be as pure as you can get, the actual active ingredient, that's correct.

Q. Okay. And you are telling us we should be actually looking at that second number then instead?

A. The second number 8.3 micrograms per litre -- milligrams per litre -- sorry, not micro, milligrams per litre represents the toxicity of the commercial product we sprayed with here. And that value is a 96-hour LC50 value.

What that means is LC50 is the lethal concentration to 50 per cent of the test organisms and what it means is that if you took a test population of rainbow trout and exposed it to 8.3 parts per million of Roundup for 96 hours half of those -- you would

expect half of those fish to die.

The value at the peak level you see here is 160 micrograms per litre or parts per billion. One part per million would be ten times higher than the hundred you see here. So basically our 8.3 would be somewhere up on the fifth floor of the hotel if we extended this graph all the way up there. And the toxicity data here is saying is that if we had that level in the water for -- going straight out for a 96-hour period, we could expect half of the rainbow trout in that system to show toxic effects.

I think this demonstrates the almost trivial nature of this exposure on a strictly toxilogical level to what would be required from our understanding of the toxicology of that species to cause toxic effects.

THE CHAIRMAN: Mr. Kingsbury, what would a normal safety factor be that you might apply for this example?

MR. KINGSBURY: There is an important distinction between toxicology evaluations that are done for human health and for environmental considerations.

The rationale for that distinction is that in human health toxicology evaluations you are

using a surrogate organism for the human, you are studying it in a mammal or a dog or a rabbit and that is part of the rationale behind why you have a safety factor.

In environmental considerations, because we are doing studies on the actual organisms that we are concerned about, we are making a direct measurement, we don't apply a safety factor per se, we don't even deal with that concept, we talk about actual measured impacts and effects.

MS. MURPHY: Q. And would the safety factor that we heard about on the last day, the safety factor with respect to human health, Dr. Ritter, would that have already been applied to this product prior to the time that it is now being tested in the environment?

DR. RITTER: A. Yes.

Q. That was yes?

A. Yes.

Q. We can't really hear you.

A. Yes.

Q. Thank you.

MR. KINGSBURY: A. Okay. Are there any questions about that figure before I move to the next one?

This next figure represents the measurements that were made of glyphosate, solid line, and it's breakdown product and you can ignore it again because basically it was never found.

In the portion of the treatment system Carnation Creek which was buffered, which was 10 metres away from the flight line of the helicopter, I point out two things. First of all, the same kind of peak associated with application and rapid decline and, again, a second input of the material into the system associated with the rain event and subsequent rapid decline.

There is a difference here in terms of, in the first situation we saw that the direct introduction was the major -- caused a higher level than the rain event.

The reason this is true is, if you will recall on your first figure, the scale on this side ran from 0 to 180 parts per billion. In this case, it goes from 0 to 3 1/2. So that this level is 1.5 as opposed to the peak of about 160 we saw in the system directly oversprayed. In the system directly oversprayed after the rain event we saw just over a hundred parts per billion and here we see somewhere just over three.

In this case it's simply -- the relative

size of these things has to be put in the context that they are both very small compared to what we saw in the overspray. It seems to indicate here anyways that more material moved in from other -- by other mechanisms than either direct spray, which should have been limited to 0 of course, or from spray drift. And one of the things that contribute to this was that there was in fact movement of some water from that treated tributary into the main channel, so some of this residue may reflect that.

Again, the magnitude of these two things indicates that in this experimental situation this buffer zone, this 10-metre buffer zone reduced the exposure which I have already described as trivial in terms of its potential for killing rainbow trout down to about a 60th, if I can make a broad generalization of what it was, simply by not having the aircraft directly over -- fly over the system.

Q. And just to help me with looking at these three pieces of information together then, and just tell me if this is right. If we are looking at parts per billion, going to the last slide you showed, the one that showed what happened in the stream with the buffer, let's just look at the highest number in parts per billion. It was 3. -- about what, 3. --

A. With the buffer in this case?
Q. Yeah.
A. The highest level is just 3.2.
Q. 3.2 parts per billion?
A. That's right.
Q. Then on the other graph that showed the unbuffered stream, the highest amount was 160 parts per billion?
A. That's correct.
Q. Is that correct? And then you were explaining to us from the previous page what the LC50 was for rainbow trout and that was 8.3 parts per million. What is that in parts per billion?
A. 8,300 parts per billion.
Q. Okay. Those are the units we should be comparing if we are looking all at the same units; is that right?
A. That's right. If we were to look for where that 8,300 would come here, it would be somewhere around the Nordair flight that is going over the motel at the moment.
Q. Okay. Thank you.
A. Okay. I have one more illustration. This one deals with an insecticide application to flowing waters. Once again this is an experimental

application carried out by our institute, was using 7,2 oil which is carbaryl -- a carbaryl formulation to a flowing stream, a flowing stream in New Brunswick. The scale here is the first 24 hours after application.

Q. Just before you go any farther. That is also in the paper, I believe, and you will find it at page 258?

A. Yes, I am sorry. It's also in the paper at 258. Once again I would point out to the fact that the exposure, the residues in water we see here clearly show that most exposure comes from the direct introduction as the spraying passes over the stream and, in this case, spraying only takes a matter of minutes and as soon as spraying ceases, a very rapid decline in residues.

To again put this in the context of a toxic level, if you turn to page 257 you will see toxicity data for forestry insecticides to aquatic organisms. You will see here that again the 96-hour LC50 to rainbow trout is 2.0 parts per million or 2,000 - some five times higher than the top of the graph here - parts per billion, so it's maybe up about the third floor. Again, indicating that there are exposure tends to be rather trivial with respect to the dose required, the exposure required to induce a toxic

effect in trout.

Q. And, again, that exposure level would have to be there for some period of time as well?

A. For a 96-hour period. You will notice that I have got data here for other aquatic invertebrates and, as I've mentioned, insecticides tend to be fairly toxic to insects and related things such as -- and included in that would be crustaceans such as the amphipod.

The values you will see here range from - and if I may do the translation to the units we are using here - to 2 to 5 for stone fly nymphs, up to 6 for daphnia, or 20 for amphipods parts per billion. So we see that for invertebrates we are now dealing down in this portion of the toxicity, the toxicities are down in this level for, again, exposures that would go straight out for some 96 hours.

I think you can clearly see from this that invertebrates -- aquatic invertebrates are much more -- are exposed to a much more significant toxicological risk in this situation than fish might be. In fact, we might expect to see some toxic effects. Now, we were actually measuring them in this case and, aside from black fly larva, saw very little evidence that there were toxic effects.

I would make one more point about this -- well, I make a couple. First of all, this is very typical of how we see pesticides dissipating when they do reach aquatic systems in forestry from direct introduction or spray drift.

I would point out that the value we see here, the initial value is very high compared to values that are measured in operational situations where we have the constraints of buffer zones, et cetera. And to illustrate that, I would make reference to a paper which I have cited and discussed to a certain length within this document on page 257 and this is a paper by Moran, et al, 1986, that summarizes the findings of studies carried out in the Province of Quebec where fenitrothion and aminocarb residues were measured for four years within aquatic systems that were within the area of their spruce budworm spray programs.

There are over 400 water samples included in this data set and I would point out that for fenitrothion, the medium concentration in those 400 samples in flowing water -- and when I say medium, I'm saying half of the samples were above and half of the samples were below - was less than 3 parts per billion. Okay. It would be way down here. For aminocarb it was less than 1 part per billion.

So it indicates that certainly making that comparison with this experimental situation where we have generated our data under directly overflying the aquatic system, we certainly have created a far greater exposure in our field experiment than we are routinely measuring in an operational situation.

I would like to now say a little bit more about the principles behind indirect effects and then move on to a discussion of the actual effects we have measured.

As I said earlier, indirect effects are determined by the degree of dependence of an organism on the environmental parameters that might be modified by direct effects. It is impossible to assess each indirect effect that might occur. You just -- you simply -- for example, you might want to say: What are the indirect effects of spraying an insecticide on the bird by possibly affecting its food?

As a practical manner we can't go out and count the before spray and after spray abundance of all the food items that any bird species might be utilizing in that forest environment. Of course, it would be different for each species we wanted to study. We have methods of doing generalized insect sampling, but we just couldn't be that precise, it's totally

impractical.

And, in light of that, the strategy that we take in doing environmental impact assessments is to identify what the net consequence of the activity might be, understanding that the final result may come from a combination of various indirect events and also perhaps direct events.

For example, you might both alter the behaviour of the prey species and alter the behaviour of the bird that was out there trying to use those prey. So what we tend to do is look at the overall community health as opposed to looking at some specific pathways.

Now, there are sometimes studies done on specific pathways but, in general, the assessment is done on a more generalized assessment of what we say are the critical parameters indicating community health.

And if we might talk about song birds, there might be a lot of ways of affecting those song birds, but what we say is critical, is saying: Is that song bird population able to continue to produce a normal number of young that are going to survive and basically, you know, carry on the population.

Implied in this kind of an assessment is

that if you determine that you are affecting the community health in some way, you might want to know why that is happening or you may simply say that: We know it is being affected, we don't know how, but we know that we don't want it affected, therefore, we will discontinue the activity.

THE CHAIRMAN: Mr. Kingsbury, how do you really solve the cause and effect relationship when you are dealing with test species that are migratory, when you really don't know what else is affecting those species outside of Ontario or the jurisdiction where you are applying a particular chemical or pesticide?

MR. KINGSBURY: That is an excellent question, Mr. Chairman, and I guess my answer is, it is to say that, if we are looking over a number of years at song bird populations we have to recognize that there may be an awful lot of things impacting them aside from forest spraying; in fact, other forestry operations.

What may be happening in terms of changes in their wintering habitat, pesticide sprays they are exposed to, et cetera, et cetera. We are, however -- and the assumption we go on to, specifically with song birds, is to say: When forest song birds enter the forest and set up breeding territories they are locked,

they have to stay in that system for their breeding to be successful.

And, in effect, what we do is we say: If the bird disappears from that system we are saying that it has not been able to reproduce there. Okay. The bird -- we are making the assumption and there is good basis for song birds for doing it -- of by saying that the bird's ability to remain within that breeding territory and produce young there -- basically, it can't get up and leave and do it somewhere else.

THE CHAIRMAN: Would you be comparing with a species its ability to reproduce at its other migratory location? I take it they reproduce -- well, for instance, a bird that flies south, it wouldn't just reproduce in Ontario; would it, would it not also reproduce somewhere else?

MR. KINGSBURY: Most migratory species only reproduce at one point in their migratory cycles.

THE CHAIRMAN: Oh, they don't reproduce elsewhere?

MR. KINGSBURY: Right.

THE CHAIRMAN: So you can't compare that. Okay.

MR. KINGSBURY: Okay. I have alluded to this strategy that we are using.

MS. MURPHY: If I can just interrupt for one second. You are going to be going on to another slide, I believe, or another overhead, but I would just make a suggestion.

MR. KINGSBURY: That's right.

MS. MURPHY: This overhead is contained in Exhibit 711, it's No. D and I suspect that if we put it up and also turn on the lights I think might -- at this present point in time, I think Mr. Kingsbury will be speaking to a number of things with respect to this overhead. It might be easier for people to take notes at this point if we turn on the lights.

THE CHAIRMAN: Very well.

MR. KINGSBURY: Thank you.

Okay. In doing our assessments, the strategy that we are pursuing might be called an indicator group approach. Now, Dr. Euler in Panel 10 spoke to you about how indicator species management approach can be applied in wildlife management, where you select a species to manage, that indicates something about the forest in terms of the wildlife values it has.

We are doing something somewhat parallel to that in that we are -- in studying the environmental impact of pesticides in forestry, we are selecting

species or groups of species to study that would indicate effects on a much broader range of non-target species in general.

The criteria for selecting those specific species tends to be their sensitivity and that can be a toxilogical sensitivity, that is certainly one primary to look, to the pesticides, the particular aspects of their biology that might make them more sensitive, for example, very small organisms; one, require a smaller dose to have an effect; secondly, tend to have higher metabolic rates which intrinsically can make them more sensitive to effects; i.e., if a hummingbird doesn't get food, you know, for even a number of hours, it's much more stressed than a mallard duck that doesn't get food for a number of hours because the hummingbird just has a higher metabolism, needs more energy and cycles it quicker.

And another criteria, of course, is just the suitability -- the availability of practical techniques to study that species or group of species. We might want to study the impacts on moose, but it's much more difficult to study impacts of pesticide on moose. In fact, in order to have a reasonable test population of moose, we would have to have a very big spray area and we would be into a very expensive type

of study.

On the other hand, almost any area of forest has a rather large population of mice or voles or shrews on it, they are smaller, they can't escape and move out of the area as easily, they have a higher metabolism and there is many reasons why in fact they are a good indicator of what might be happening on a broader range of mammals. That is basically the strategy.

The bottom line is that our impact assessments primarily are carried out on these organisms; plant communities and, of course, that relates primarily to herbicides where plant communities are most sensitive to impact; non-target invertebrates and that, of course, is really the starting place for insecticide impact evaluations; forest song birds, and small mammals and fish.

What we consider the critical assessment parameters for these groups; i.e., the thing that we really want to assess for our evaluation purposes are spelled out in this column. For plants it's the community structure and the succession that is going to take place. So we have a time scale built in there, of course, what is going to happen over the long run in terms of plant succession following the pesticide

application.

For non-target invertebrates we look at the process functioning: Do these groups continue to play the role in the environment which is the importance attached to them.

Now, that is not to say that for some people or for some species there might be another value we want to preserve; maybe an aesthetic value, maybe we want to attach particular importance to one given species for an aesthetic value. And I'm not making an assessment on the appropriateness of doing that, I'm simply saying: That's not the approach that we generally use.

THE CHAIRMAN: How do you become aware of what the process functions are of a particular non-target invertebrate? In other words, you can be testing all you want, but if you don't really understand the process function well of that particular specie, won't that affect all of your information that you gather from these tests?

MR. KINGSBURY: Absolutely, and it's -- you know, it's very true that our ability to defect effects is linked into our ability to understand the system and how it works.

THE CHAIRMAN: So I take it you choose

ones that you think you understand reasonably well?

MR. KINGSBURY: Right. And for some groups of organisms, you know, that may be the reason why we don't have as much knowledge about impacts on them as others. Not a great deal of work is done on the microbiology, you know, the bacteria in forest soils partly because it's an area that we tend to know less about than something like the biology of moose.

For song birds and small mammals, the critical assessment parameter we are looking at is basically reproductive success, production of young and the survival of those young to breeding age. And for fish the critical parameter is basically the size and structure of the population, and by structure I'm including things like its growth rates, how well is it growing.

The rest of my presentation is going to be my attempt to summarize for you the available data pertinent to this kind of an assessment strategy for the pesticides that we are considering for use in Ontario. It basically is trying to summarize the data you will see spelled out in some detail in the ESSA Document supplemented by other data of which I'm aware that isn't in the ESSA Document.

Starting at plant communities. Plant

communities are, of course, our starting point with herbicides. We want to assess, first of all, the direct effects on the plant community and on plant succession. And given that herbicides tend to have rather low toxicity to other organisms, their main impacts on other organisms tend to be because of their direct effects on plant communities.

As in environmental effects, the changes that occur because of applying a herbicide on plants within the plant -- to other organisms may be no different than the environmental effects if you changed the plant community by some other technique; i.e., another type of tending operation that had the same impact on the sequence of plant succession on the site. And I think that's an important consideration.

With insecticides, impacts on plant communities are primarily preservation of the existing plant communities. That's the idea of the insecticide use, basically to maintain the plant community that's there on the site; you want to prevent the budworm from harvesting the site, you want to keep it alive and healthy, and you want to do it because you want to maintain the values associated with that, whether it be as timber to be harvested in the future or as wildlife habitat.

For non-target invertebrates, briefly I will spell out some of the specific invertebrates we are considering there. They can be the prey items for birds or fish or mammals, so I am including in this both terrestrial and aquatic invertebrates; they can be insects that pollinate plants - and, of course, there are all kinds of invertebrates out there, I am talking about the ones we primarily study and evaluate - they can be the predatory insects or the parasites that keep other insect populations in check; or they can be invertebrates that are involved in nutrient cycling in breaking down litter, returning things back -- nutrients back to make them available for plant production.

As I have mentioned, these are primarily assessed through measuring the rate and the success of the ecological processes they drive. Okay. For example, we measure effects on pollinators ultimately at the level of saying -- measuring fruit set in the insect pollinated plants that depend on them.

THE CHAIRMAN: What do you mean by the term fruit set?

MR. KINGSBURY: Fruit set basically is when you have a flower you require by some mechanism transfer of pollen, you know, basically the male

genetic material to the ovary in the female and in an insect-pollinated plant, that requires the insect to actually physically transfer it from one site to another.

Fruit set can also occur by wind-blown pollination or self-pollination. A lot of plants simply have evolved so that they can get those two things together on their own without anything else.

THE CHAIRMAN: Perhaps I am just not understanding it. What does the term fruit set mean; does that mean the transfer mechanism?

MR. KINGSBURY: Fruit set means the successful transfer of a genetic material so that a viable seed capable of producing another plant by sexual reproduction can occur.

MS. MURPHY: Q. So it is something you can see; is it, something you can actually see and see if it happened?

MR. KINGSBURY: A. That's right. Is that clear, Mr. Chairman?

THE CHAIRMAN: Yes, thanks.

MR. KINGSBURY: Okay. Now, that's not the only way we do it. Like, sometimes we do actual field evaluations, say, of direct toxic effects. So we might take bees out into the area and see whether any

of them are killed, as a for instance. But again I am saying that really the critical parameter is that measurement of process functioning.

What are the known effects on invertebrates for herbicides, again, thinking in the nature of the site where we primarily have things that have been recently harvested. When we talk about non-target invertebrates we think primarily of things like soil fauna, and the impacts of the herbicides we are considering on soil fauna are some orders of magnitude less than the impacts that tend to be related to the changes in that environment that have already occurred because of harvesting.

We have taken that soil and taken away all the vegetative overstorey, opened it up to sunlight, physically disturbed it by our equipment, et cetera, perhaps changed drastically the soil moisture content and those kinds of changes are far more significant in terms of impacting on soil fauna.

MS. MURPHY: Q. And we heard earlier about changes in temperature. Is that another one of these parameters that you might be talking about?

MR. KINGSBURY: A. That's right, yes. of course, soil is going to be warmer after the canopy is removed. They have far more impact than the

applications of the herbicides themselves. And part of our knowledge of this comes from work done in agricultural situations where these same things occur.

In terms of aquatic invertebrates, herbicides tend to be at very low toxicity to aquatic invertebrates and have little effect. In fact, materials like glyphosate and 2,4-D have registrations for aquatic weed control and, in being registered for those, the registration process has said that they do not have unacceptable impacts on those groups. They are allowing an application that directly puts them into the aquatic system.

In terms of honey bees, herbicides are virtually non-toxic by the standards we use to honey bees and to other invertebrate groups in general.

For insecticides, dealing first of all with BT, bacillus thuringiensis, which is a bacterial insecticide, as you have heard, this insecticide affects strictly insects, the order lepidoptera, caterpillars, i.e. It will affect some but not all non-target caterpillars out in the environment and we are dealing with a very large complex of species.

Field and lab studies have confirmed the lack of impact of BT on bees or other aquatic or terrestrial invertebrates.

The other registered insecticides that we are talking about in this process are all broad spectrum chemical products and, being broad spectrum, they are not as selective as BT, they tend to produce a knockdown of insects from sprayed trees for a short period of time after spraying, but we know from studying what is left on the trees and what's come down that this represents only a small portion of the resident invertebrates in trees.

All of these chemical insecticides are fairly toxic to bees and can in fact cause some mortality of bees that are out and exposed to spray droplets. Aminocarb certainly is considerably lesser in its effects in this -- on bees than either carbaryl or fenitrothion.

In terms of impacts on pollination of forest plants, measurements such as fruit set measurements have shown that pollination as a process can occasionally be impacted, that there is a high degree of variability depending on the plant species and this is true within spray blocks, that there is -- we certainly have indirect evidence from this that the mortality of pollinators across a spray block can be very patchy.

In terms of the processes of parasitism

or exerting -- or predation that exert pressure on other insect populations, there is no evidence that these processes are affected by the spraying of these chemicals. We can measure the rates of parasitism within the pest insect in sprayed and unsprayed blocks and these kinds of studies have shown that these parasitism rates are not impacted on, are not affected by these -- either the chemical or biological insecticide we are talking about.

With respect to aquatic invertebrates, aminocarb certainly again has relatively little effect on aquatic invertebrate communities. Fenitrothion and carbaryl, on the other hand, sometimes cause modest disturbance, and when I say that I am trying to capture both sub-lethal effects such as the invertebrates being affected to the extent that they lose their grip on the substrate in a flowing stream and end up drifting down the stream, which may or may not represent eventually dying, in many cases they recover. And I am also capturing the idea of disturbances where the populations resident on a site might be affected.

There is some evidence for this, it certainly is sporadic. Some of the data indicating effects is generated at levels that are higher than the levels of use that we are talking about, the

application rates we are talking about using here in Ontario.

In forest ponds in a static water situation there is a little more evidence for impacts of fenitrothion and carbaryl on invertebrates, particularly under conditions under which these materials are found to be more persistent than normal, and that tends to be small acidic ponds which have very dark water so there is a limitation of light penetration and it limits the role that light plays in the breakdown of those materials. And, in those cases, for some species of invertebrates we can in fact -- we have in fact found evidence of population reductions that persist for some time.

THE CHAIRMAN: Why within an acidic pond do you have less light penetration, because I would have thought that because most of the living plant material is probably not present you would have more light penetration?

Is not one of the tests of some of the lakes that you can see right to the bottom 30 feet down, probably that the lake is dead in terms of life?

MR. KINGSBURY: That's correct, Mr. Chairman. In fact what I was trying to capture was that you require both acidity plus a situation where

there is low light penetration. They are not combined; they are two separate factors that both appear to have to be there. The evidence for this primarily comes from small forest ponds in the State of Maine, bog pond situations.

Okay. I hopefully can get through this in a fairly reasonable amount of time. I know it is a bit ponderous, I am trying to capture a lot of data very quickly.

Moving on to forest song birds and small mammals. In terms of herbicides, again herbicides that we are considering have low toxicity to forest song birds and small mammals. The nature of the sites, that they have been recently harvested certainly limits the populations that are there at the time of application and that can also be limited by the time we apply the material. If in fact we are applying the material outside of the breeding season of song birds, chances are they won't be there.

MS. MURPHY: Q. So is the idea then that you're saying there is low toxicity and low exposure?

MR. KINGSBURY: A. That's right. Certainly the vast majority of the forest song bird complex wouldn't be found breeding on a recently harvested site because most of those species are

adapted to more advanced vegetative stages.

The long-term utilization of those sites that are sprayed with herbicides by song birds and mammals, again, will reflect the changes in the plant communities that will arise on that site and that have been influenced by the herbicide's actions.

I will return to the species complex that initiated -- that was on the site prior to harvest may be expedited in the long run if the effect of the herbicide is to turn that back into a mature conifer site, but in the interim, it will be the stages that it goes through, each of which will provide opportunities, different opportunities for species that have different habitat requirements.

Moving now to the effects of insecticides on forest song birds and small mammals. BT has been found to have no impact on bird or mammal populations. In addition, there is little evidence to support the contention that BT's impacts on caterpillars in general could lead to an indirect effect on bird populations or mammal populations through the impact on their food supply.

With respect to aminocarb and carbaryl, there is a very extensive database available for both these materials. They show little impact on song birds

or mammals. Field studies of carbaryl have been done at up to six times the operational application rate, again, without showing adverse impact on bird populations.

For fenitrothion there has generally been shown -- it has generally been shown not to affect bird populations in total at registered application rates, but there is a considerable weight of evidence indicating sub-lethal effects on some species.

There is certainly debate within the scientific community as to the significance of those sub-lethal effects; mostly they refer to the suppression of an enzyme within song birds that we know is a temporary and transient effect, that that enzyme activity will recover, and really the debate tends to focus on what is the significance of that enzyme being depressed for a period of time after spraying.

But I would again emphasize that in terms of the parameter of the ability of song birds populations to reproduce, the conclusion of a very, very large body of data is that we cannot separate out a fenitrothion effect on those song bird populations.

In terms of actual mortality of individual song birds, the numbers of song birds that have been reported picked up with fenitrothion is in

terms of a handful for a number of years.

THE CHAIRMAN: Mr. Kingsbury, what are the groups of chemicals that are reputed to decrease the thickness of egg shells for some species of birds; is it the DDT group?

MR. KINGSBURY: That's right. The effect you are talking about has been associated with persistent chemicals, and it goes beyond pesticides, that persist in the environment and also that bio-concentrate and bio-magnify in the environment.

THE CHAIRMAN: And you are saying that doesn't occur in the forest ecology situation?

MR. KINGSBURY: Exactly. If I might just go back to --

MS. MURPHY: Q. Just to clarify, I don't think -- were you saying it doesn't happen in forest ecology or it doesn't happen with the registered products you are discussing?

MR. KINGSBURY: A. That we are talking about using in Ontario now, right.

MR. MARTEL: Well, what has happened then to the loon population and the effect or the concerns several years ago expressed that they weren't reproducing simply because the egg shells weren't thick enough to allow them to be born? What was causing

that?

MR. KINGSBURY: I wouldn't pretend to have any expertise in, you know, in that specific issue that you've brought up. The only relevance to what we are doing here today I guess would be simply to indicate that the loon is not a species that you would expect any kind of exposure to these materials, given its nesting sites and the places we find it in the province.

I think that the decline in the reproductive success of the loon in Ontario is attributed to a lot of factors and my anecdotal perception is that one of the major ones is disturbance of nesting sites, not necessarily implying a physiological effect on the eggs, but the fact that loon reproduction is a very slow process, that normal reproduction is measured in terms of successful fledging of, you know, an individual or two at the most, you know, per year and that it's very sensitive to water level changes, to disturbance by humans, et cetera, and there may be an environmental contaminant component as you are suggesting, but I am not aware of it and certainly my opinion is it has no linkage to forestry use of pesticides.

Just to finish off my discussion of

fenitrothion and forest song birds, I would point out that, again, there is experimentation in a block that received many times the normal application rate of fenitrothion, over five times. This was a study where there was extensive involvement by a number of agencies including the Wildlife Service -- the Canadian Wildlife Service and that this study, despite the fact that we have shown sub-lethal effects to often occur with fenitrothion, failed to show either evidence of any kind of mortality within the song bird population or an impact on its ability to reproduce.

In terms of small mammals, there is little evidence that any of these chemicals affect small mammals in field populations -- in field situations.

MS. MURPHY: Q. And there you were speaking to those chemical insecticides?

MR. KINGSBURY: A. That's correct. Finally dealing with fish. In terms of herbicides, as with birds and animals, commercial products that we see are of relative low toxicity to fish.

In some commercial products, such as glyphosate, there are inert materials which are included in the commercial product in order to make the product do the job it's intended to. These are

materials such as surfactants or solvents or stickers.

Q. What is a surfactant intended to do?

A. A surfactant basically helps to get the material into the plant system so it can function there. It has basically a physical role of helping to get it into and through the plant surface -- on to and through the plant surface.

Some of these inert -- so-called inert ingredients can in fact be more toxic and are more toxic than the pesticide, the actual active ingredient itself, and this is true of the commercial formulation of glyphosate, Vision, where as we saw in my evidence earlier the commercial product is considerably more toxic than the pure pesticide material itself.

Q. And you are referring to Table 16.5 in your paper at page 259 that you were showing us earlier; is that correct?

A. That's correct. The point to make here is that both at the laboratory and in the field evaluation procedure that I described in some detail in the registration process, the data is generated using the commercial products. If the manufacturer were to make a significant change in that commercial product, new data would be required by the registration process in order to register that material. And, again, Dr.

Ritter expanded on this to a considerable degree yesterday.

I have already shown you examples of the type of exposure we see with herbicide applications and indicated to you that the risk to fish are minimal, if not miniscule.

With respect to the insecticide impacts on fish, again, BT is not toxic to fish and has no impact on them. Again, there are extensive databases available on the effects of the aminocarb, carbaryl and fenitrothion for their impacts on fish; these are both field and lab studies, and they have shown that are lethal or significant sub-lethal effects do not occur at operational application rates.

In terms of indirect effects, again, I would state that despite speculation as to the potential indirect effects on fish that might occur from impacts on their food organisms, there is little evidence to demonstrate that such effects occur. On the contrary, it's well documented that following the spraying with broad spectrum chemical insecticides, fish often exhibit increased feeding on both terrestrial insects that are knocked into the stream and aquatic invertebrates whose behaviour might be affected to make them more susceptible to fish

predation.

It's a transient effect, it only lasts for the first few hours after a spray application, but it has even been shown to basically increase the growth rate of fish for a short period of time. At the same time there is no evidence that it indicates a significant pathway into the fish of residues capable of causing an impact on them.

In general, fish populations and critical parameters about them such as their growth rates and reproductive abilities are not affected by the use of the materials we are considering.

That is a very brief review of the data, the detailed datas and the references, the scientific literature are contained within the ESSA Document.

Q. And I would just ask you to take the ESSA Document then in hand at this point and what I believe you are going to do at this stage is just take us -- identify for us where in the document the conclusions of that group can be found, and that you had a couple of comments to make about those conclusions before you complete your evidence?

A. That's correct, Ms. Murphy. If I could ask you then to -- if I can walk you through the conclusions of this document and I will summarize them

and make a few comments regarding them.

Turning first to page 36 to 39, and these are conclusions regarding basically the residues of these pesticides and their fate in the environment.

My summary would be herbicide residues primarily end up in soil and plants; insecticide residues primarily end up in foliage. The herbicides and insecticides used for timber management in Ontario are generally not very persistent. I would note a few exceptions such as the persistence of simazine in soil which tends to be greater than for the rest of the materials, of 2,4-D in blueberries, and of carbaryls and fenitrothion in water and sediments of those small dark acidic ponds that I made reference to earlier.

And I would add to the conclusions in this ESSA Document one that I think should be added to that list and; that is: Residues of fenitrothion persisting in the cuticular waxes of conifers. With those exceptions, I would concur with the statement that the pesticides used in Ontario are not very persistent.

None of these pesticides show evidence of significant leaching, show evidence of significant bio-concentration or bio-magnification.

Turning to pages 43 to 45. Here we have

conclusions regarding direct toxic effects of the pesticides we are considering. I would summarize them as: The forestry herbicides in use in Ontario are very unlikely to give rise to toxic effects on terrestrial animals. I would note this group of conclusions pertains to the terrestrial eco-system.

With respect to insecticides, the direct toxic effects of BT are limited to non-target caterpillars and they are modest. Aminocarb, carbaryl and fenitrothion, the broad spectrum insecticides we were discussing, have a wider range of direct effects on non-target invertebrates, but they have negligible or limited impacts on ecological processes.

These three materials that I mentioned do not affect the overall populations or reproduction of song birds and small mammals, but there is some evidence for direct toxic effects on sensitive song bird species for fenitrothion.

I would add the comment here that I have some difficulty agreeing with the conclusions here that suggest there is evidence for effects of aminocarb on small mammals or for fenitrothion on small mammals and amphibians, and I would suggest that in those areas perhaps this conclusion reflects a lack of knowledge of the entire relevant database or an overemphasis on

studies with which I feel there is considerable evidence to the contrary.

If I could take you now to pages 63 to 64 and the conclusions on food chain effects. I would summarize these as saying that insecticides but not herbicides alter, to a modest extent, the amount and distribution of prey available for insectivorous birds and mammals.

In my opinion, for the vast majority of predator/prey relationships, there is simply not a large enough or a broad enough impact on the prey organisms to result in significant effects on the prey species -- predator species, sorry.

MS. CRONK: I'm sorry, Mr. Chairman, could the witness repeat the last part of that, I didn't get it.

MR. KINGSBURY: The second part of that conclusion?

MS. CRONK: Or the whole thing actually.

MR. KINGSBURY: Okay. Summarizing it again that insecticides but not herbicides alter, to some extent, the amount and the distribution of prey that's available for insectivorous birds and mammals.

In my opinion, for the vast majority of predator/prey relationships, there is simply not a

large enough or broad enough impact on the prey species to significantly impact on the predators.

MS. CRONK: Thank you.

MR. KINGSBURY: You are welcome.

We are almost at the end. Turning to page 67 to 68 and here we have the conclusions regarding habitat effects. As I have mentioned for insecticides, the impacts of habitat -- the impacts on habitat are primarily preservation of existing habitat.

Herbicides, on the other hand, change the vegetation present in the treated area and modify the rates of forest succession. They change these in a way that is similar to other tending practices and they change them on sites where previous activities associated with timber management have already dramatically altered the vegetation in the recent past.

It is, in fact, difficult to separate out the effects on wildlife that come through the herbicide-induced changes from the overall effects of the entire range of activities on that site. I would, however, say that the herbicides' effects would likely be considerably less in terms of their changing modification of the habitat than the effects of other activities like harvesting.

And finally, on pages 80 and 81, the

conclusions regarding effects on aquatic organisms. I would summarize these by saying that there is an abundant literature supporting the conclusion that toxic effects and significant sub-lethal effects on fish have not resulted from the use of these materials in forestry.

Chemical insecticides have been found to sometimes have modest impacts on aquatic invertebrates, communities, particularly in certain standing water conditions and, again, I have made reference to small ponds with highly coloured waters and acidic water quality.

There is no evidence that aquatic communities are impacted through habitat changes resulting from the use of these pesticides, with the possible exception of where insecticide spraying maintains streamside cover.

My final conclusion then would be that the pesticides registered for use in forest management have negligible or limited impact on the ecologically critical aspects of sensitive non-target organism communities.

MS. MURPHY: Okay, thank you very much. That is the end of Mr. Kingsbury's evidence. I have a couple of minor matters to do for the record and I

could do that now and then I would suggest it is probably a wise time to take the luncheon break and, as I say, these are minor.

It was drawn to my attention that in Exhibit 711, if you just take that exhibit and look at page B, the title at the top of that page should be amended so that it says: Generalized Pathways of Potential Pesticide Effects. This one is the one that deals with the general sort of situation and it's the following one that deals with the specific situation. So if you just amend the title to that.

MR. CASTRILLI: What page was that?

MS. MURPHY: I'm sorry, it's page B of Exhibit 711. And you will see at the top the title of it -- the title of that document makes reference to insecticide. That should simply be changed to pesticide, so it deals with both insecticide and herbicide.

One other matter for the record I just wanted to point out to you. Mr. Kingsbury was talking about the classification, the registered classification for forestry products. Just for your information there is a description of the classification system and all of the various types of pesticide classifications in the paper that was submitted by Dr. Ritter and you will

find that discussion starting on page 94 of the Statement of Evidence for Panel 12 in Volume I, that is Exhibit 603A, and that discussion, as I said, begins on page 94 and goes to 96.

THE CHAIRMAN: Thank you.

Ms. Cronk, are you going to require additional time other than the lunch hour?

MS. CRONK: My only concern was when you were intending to return.

THE CHAIRMAN: Well, we are intending to return around two o'clock.

MS. CRONK: That would be fine, sure.

THE CHAIRMAN: Thank you.

MS. CRONK: I should indicate to the Board I will make every effort to finish today, but given the length of time this morning that was taken in-chief, it may not be possible, but I will certainly try.

THE CHAIRMAN: Okay. We will adjourn until two o'clock.

Thank you.

---Luncheon recess taken at 12:38 p.m.

---Upon resuming at 2:05 p.m.

THE CHAIRMAN: Thank you. Be seated, please.

Ms. Cronk?

MS. CRONK: Thank you, Mr. Chairman.

CROSS-EXAMINATION BY MS. CRONK:

Q. Mr. Kingsbury -- is that better?

MR. KINGSBURY: A. Yes.

Q. Mr. Kingsbury, I introduced myself to you earlier today but, Dr. Ritter, we have not met. My name is Eleanor Cronk and I'm one of the counsel representing the Ontario Forest Industries Association and the Ontario Lumber Manufacturers Association. And perhaps, Dr. Ritter, if we could, I could put my initial questions to you.

You will recall that on Tuesday during the course of your evidence you used a number of overheads, Exhibit 709, and Ms. Murphy distributed photocopies of them.

Do you have a set of the photocopies?

DR. RITTER: A. Yes, I do.

Q. All right. If I could ask you to look at Exhibit 709A, the first page of it, and I simply want to ensure that I understand the background to some of the information that you have provided to the Board.

As I understand the first page of the exhibit, it simply shows the federal -- the various

federal government agencies involved in the processing of submissions for pesticide registrations; is that correct?

A. Yes, it is.

Q. Only one of which is your own, that being Health and Welfare Canada?

A. That's correct.

Q. And the next page B depicts the organization of your own department?

A. Yes.

Q. And if we go through the next three pages; that is, C through to E, they set out the types of studies required to support a registration application that you described in some detail to the Board; is that correct?

A. With regards to helth and safety studies, yes.

Q. All right. But that was the point that I was coming to, Dr. Ritter.

A. Yes.

Q. Do I understand it correctly that all of the studies that you have described are specific to your own department and to the issue of examining health and welfare implications of a pesticide registration application?

A. In fact it's even more specific than that, it is that and something less. The studies that I have described are specific to the evaluation of occupational and bystander health with regards to a pesticide submission. And the studies which I have provided here, the studies which I have described do not include an evaluation of food residues.

So there would be additional studies that would be required for applications of pesticides to food products.

Q. And are they required by Health and Welfare or by Agriculture Canada?

A. They are required by Health and Welfare. Food residues in Canada are regulated under authority of the Food and Drug Act administered by the Minister of Health.

Q. Thank you. Then with that elaboration, do I have it then that all of the studies that you outlined and discussed in some detail for the Board are those particular to the responsibilities of your department; that being Health and Welfare?

A. That's correct.

Q. All right. And am I also correct that a large number of studies and data production, if I can describe it that way, is required of a pesticide

registration applicant from the other federal agencies identified in Exhibit 709A?

A. Yes.

Q. And all of those studies are increment to those required by your own department?

A. I don't think I would construe them as incremental, but rather additional.

Q. All right. Would you agree with me as a general matter, Dr. Ritter, based on your experience in the process of application review that from an applicant's perspective a very large number of studies are required by the federal regulatory authorities to support an application for registration?

A. Yes, both nationally and internationally. I have been told many, many times by both the regulated and the regulators that we have what many consider to be among the most stringent requirements in the world.

Q. Do you regard it as such, Dr. Ritter?

A. Yes, I do.

Q. And when you make that statement are you referring to the quantity of material, the extent of the database that's required, or as well to the nature of the database that's required?

A. All of that, in addition to the

intensity of the review.

Q. Thank you. So that from an applicant's perspective then, if I could ask you to wear that hat for a moment if you could, are we agreed then that an applicant is required to submit a large database, a great number of studies to support an application; that's the first item?

A. Yes.

Q. And as you have outlined, the data and the studies which are then submitted are subject to what some regard, including yourself, as one of the most stringent systems in the world for this kind of registration evaluation?

A. Yes.

Q. Is it also fair to suggest, Dr. Ritter, in your experience that the production of that database as required by Canadian federal regulatory authorities is a very costly proposition for a registration applicant?

A. Yes.

Q. And based on your experience, can you assist the Board as to how long it takes, on average - I recognize there is exceptions to every general proposition - but how long does it take on average for an applicant, from the initiation stage of the study

prepatory work to the point of data submission to complete, compile and submit the necessary studies in support of a registration application?

A. With regards to studies submitted pertaining to health and safety only, because I'm not really aware of the time required for the other components, typically it could take 10 years.

Q. And that is typical?

A. That's typical.

Q. And would it be fair to suggest that depending on the nature of the studies required by other agencies and depending on whether they can be conducted in tandem, if you will, with those required by your department, that time period could be lengthened?

A. It could be, yes.

Q. All right. And after submission of that database to your department, how long typically does your department evaluation process then take; what kind of time frame is an applicant looking at from the time your department gets it to the time of evaluation response?

A. I would like to change your question a little bit, if I may. The typical turnaround time from submission to initial response in our hands is of

the order of 8 months to a year, but I would hasten to add that rarely has an application ever been approved following an initial submission.

So that these submissions typically are in review, are in evaluation and negotiation for lack of a better term for periods of two, three, five years in some cases where some questions may be generated which, in turn, will require the generation of additional data and so on and so forth.

Q. All right. So that from, again, an applicant's perspective, a manufacturer of a potential pesticide product could be looking at anything from 10 to 15 years -- I'm sorry -- yes, 10 to 15 years from the time of initial preparation of these materials to the time of final review assessment by your department and your department alone?

A. I would say that represents more often than not the extreme case, but it's not unrepresentative. That order is correct.

Q. All right. Something in the vicinity of 12, 13 years being not atypical?

A. That's right.

Q. All right. And then there is the review involved by all the other federal agencies as well?

A. That's right, but that may be going on simultaneously rather than consecutively.

Q. And in terms of the in tandem review, if I can put it that way, by the various agencies who have input into the evaluation process, typically are these data packages, are the applications submitted in progress by an applicant, or as a bundle, as one if you were?

A. In our hands at least we are reluctant generally speaking to accept results of studies which are in progress. The nature of the studies which we examine are such that results in progress are often not terribly informative.

If I can just very quickly illustrate with an example. If we are looking at a cancer study which typically will run two years and may take up to four years to report, if one were to submit results of that study when it were halfway through, because tumors often occur at the end of the study, it would not be surprising if tumors did not occur halfway through the study.

So, in that regard, submitting results from a half completed cancer study are really not very informative for the purpose for which the study was conducted. We are reluctant to accept studies other

than to put them on the shelf and await completion of the study.

Q. All right. So that a value for the reason that you have outlined, evaluation by your department takes place when the database is complete?

A. That's right.

Q. And submitted as a whole by the applicant; is that right?

A. That's right, with one or two notable exceptions. As we discussed the other day, full-scale field exposure studies may be conducted during the first semi-operational part of the registration process; that is, during a larger scale experimental use permit because it's the only way that actual field conditions can be replicated for the purpose of gathering exposure data.

But notwithstanding those sorts of exceptions, generally speaking, we would require submission of the complete database before evaluation would begin.

Q. To the extent that you are familiar with practices of the other involved federal agencies, is that representative of the practices of those agencies as well?

A. It depends really on the agency you

are referring to. As Mr. Kingsbury pointed out this morning, many environmental impact studies I believe are actually conducted in many instances -- I shouldn't say many -- some environmental impacts studies are conducted after registration because it's impossible to gather large-scale operational impact data from small-scale research trials.

So I think in the case of some of the other agencies it's a mix of both. There certainly is quite a bit of data that is required in the pre-market context, but there is a substantial amount of data which is gathered in the post-market context.

Q. Just looking at the pre-market time frame because it's that step or process, if you will, that results in either acceptance or rejection of a registration application; am I right?

A. Yes.

Q. All right. Just dealing then with the pre-market database, am I correct that the federal agencies in addition to your own typically have a procedure in place akin to your own and; that is, they receive and wish to receive for evaluation the database packages as a whole?

A. Yes.

Q. All right. And then, as you said,

once approved -- a decision on approval is forthcoming post-market information can be dealt with in accordance with what's appropriate for the nature of the study?

A. Yes.

Q. All right.

THE CHAIRMAN: Ms. Cronk, can I just interject here.

Dr. Ritter, does that mean in effect that in order to have complete data on exposure in order for you to make the evaluation and then register before allowing it on the market, most of these substances or insecticides or pesticides will have been registered in some other countries that allow for use prior to having the exposure data?

DR. RITTER: In other countries, yes.

THE CHAIRMAN: In other jurisdictions. So in other words, you would be deriving some of your exposure data from the use of the product in some other country that allows the product on the market prior to having the complete set of data because we wouldn't allow it on the market here until you have that data; is that correct?

DR. RITTER: Yes. In fact, that occurs quite frequently because other countries do not impose the requirement for human exposure data which we do in

Canada, it is very frequently the case where one will submit human exposure data which has been generated in another country.

In contrast to the environmental impact data which is very dependent on climate and a variety of other physical environmental parameters, human exposure data is less sensitive to those variables and, consequently, exposure data which may have been generated in the United States or in Europe is as useful as exposure data generated in Canada provided that the use and application and equipment are similar.

THE CHAIRMAN: And that was my next question: Therefore, in most of these studies you are relying on externally generated data and, therefore, you are happy with the quality of that data?

DR. RITTER: I think I would put the emphasis on the quality of the data rather than the venue in which it has been generated. The emphasis -- the criterion is based on the quality of the data, not the geographic locale where it may have been generated.

There are conditions which we impose and apply to the evaluation of this data, and if these conditions are not met, even if the exposure data had been generated in Canada, it would be considered equally unacceptable.

So that we are less concerned with what geographic region has formed the basis for the generation of these data and we're more concerned with the quality of the date per se.

THE CHAIRMAN: But you would necessarily have a ranking I suppose of which countries generate the type of data that you would feel more comfortable relying on because of the methods they use than, say, some other countries?

DR. RITTER: I wouldn't say we have a ranking but I think, as is the practice in any discipline, after having done this for some years, one has a sense of more reliable and less reliable sources.

THE CHAIRMAN: Okay.

MR. MARTEL: But you do rely on -- I think you said, and maybe I wrote it down incorrectly, that you do rely on data after it has gone on the market here, the process goes on of reviewing the material?

DR. RITTER: In the context of health and safety?

MR. MARTEL: Yes.

DR. RITTER: No.

MR. MARTEL: No?

DR. RITTER: No. All of the health and

safety information, all of the health and safety information is required prior to registration. The only exception to that is where there may be no human exposure data available from another jurisdiction and where that exposure data may be required to be generated for the first time to support the Canadian petition we may, under circumstances, agree to the generation of that exposure data in Canada under restricted experimental use permits.

But with that exception noted, and I should perhaps add that it doesn't happen all that frequently because the chemicals, for a variety of economic reasons, are rarely introduced into Canada first. So that more often than not there is human exposure data that is available from other jurisdictions.

All of the health and safety data, all of the toxicology data which I described must be evaluated prior to registration.

MS. CRONK: Q. A number of matters arising out of that discussion, Dr. Ritter. Dealing first with one of the points you discussed with the Chairman, I have understood you to say that in many cases exposure data or human health data is available at the time of evaluation by Canadian authorities

emanating from other jurisdictions; is that correct?

DR. RITTER: A. That's correct.

Q. So in that sense, to the extent that it is available, a known to you, and presumably the applicant would make you aware of that--

A. Yes.

Q. --if there was information that was relevant to the review process; isn't that fair?

A. Yes.

Q. To the extent that it is known to you and available to you, that forms a constituent part of the database that is available to your department for the evaluation?

A. That's correct.

Q. All right. Would it be also fair to say, however, that it should not be taken from that that there is not data dealing with human health effects emanating from Canadian scientists, Canadian sources that is also taken into consideration where it exists?

A. That's correct.

Q. All right. Would it be also fair to say that in many situations, therefore, you are dealing with information from both offshore and from within this jurisdiction in point of source?

A. Oh, absolutely, yes.

Q. All right. And with respect to the question or the discussion that you had with Mr. Martel, you have indicated that all of the -- let me rephrase it. I would ask for your confirmation if I understand this correctly.

All of the requirements imposed upon an applicant by your department in terms of data and information production to support an application must be submitted and reviewed in full before a registration decision is made; is that correct?

A. That's correct. Now, in saying "all", as I think about that on reflection, I am sure one will be able to find an example of where perhaps that principle has been violated. So in the interest of precision, I should perhaps say in the vast overwhelming majority of cases.

Q. All right. I will take that, thank you. Having said that, however --

THE CHAIRMAN: It sounds like a very lawyer-like qualification.

MS. CRONK: I kind of liked it.

Q. I understand that to mean in almost every single case?

DR. RITTER: A. That's correct.

Q. Thank you.

A. I can't think of an exception as I sit here, but I'm confident that there is one.

Q. Thank you. I don't have it, if it puts your mind at rest, and nor am I interested particularly in having it.

So having said that, what I am interested in though is the flip side of that, Dr. Ritter, to make myself clear and; that is, that if human health relevant information is made known to you or becomes available in the scientific community relevant to a product that has received registration approval, although that approval has already been granted, do I understand correctly that obviously your department would look at that information?

A. We would not only look at it, but we would act on it and there are a number of very notable examples in the last three to five years within contemporary history that we could refer to where I think the action the department has taken is evident.

Q. All right. And so in that sense, when Mr. Martel, as I understood the question, suggested to you that the process was ongoing and that there was post-market information considered by your department; that is correct?

A. That's right.

Q. All right. And am I also correct that in both the pre-market stage of evaluation and the ongoing post-market stage of evaluation, your department or other federal agencies involved in the process can require an applicant or manufacturer to produce additional information?

A. Oh yes.

Q. Additional data?

A. Yes.

Q. And that applies both before registration is granted, if at all, and after, if it is granted?

A. Yes.

Q. And, similarly, the jurisdiction exists both for your department and for the other involved federal agencies to require retesting?

A. Yes.

Q. A replication of results study?

A. Yes.

Q. And, for example, that different dosages be used in a manner similar to the -- sorry. That, for example, retesting could be required requiring different dosages, a different rate of application, a different field study circumstance?

A. Yes.

Q. All right. All of that results in more time for the applicant, if required?

A. Yes.

Q. All of that results in more cost for the applicant, if required?

A. Yes.

Q. All right. Can we deal with the cost side of the issue then. I am interested, if you are able to assist the Board, in providing the Board with a perspective on what the economic implications of an application procedure of this kind are for an applicant.

You told us what the time frame is, roughly 10 to 15 years, not atypically 12 years or so. What, in your experience, if you can assist the Board, are the costs associated for the applicant from the initiation of the preparation of their required studies and data to the time of initial submission. Let's just take it that far for the moment. In approximate terms can you assist the Board?

A. The numbers that I have seen which have been circulated by both the Environmental Protection Agency in the United States and by the National Agrochemical Association in the United States,

the trade association representing manufacturers of pesticides, currently runs between 15 and $20-million.

That's to satisfy U.S. registration requirements which are, in many cases, identical to Canadian and, in some cases, may be different such as the environmental impact. They would be additional to those data requirements in the United States.

Q. And that is then at the time, as I suggested, of initial submission?

A. That's right.

Q. And that is in U.S. dollars presumably--

A. Yes.

Q. --if it emanates from U.S. sources?

A. Yes.

Q. After the data package is then submitted, there is the course of review by the federal agencies that are involved in the evaluation process itself and that, you would agree with me, represents a different form of cost, this time to the taxpayer?

A. Yes.

Q. All right. Can you help me as to, based on your experience, the person hours involved in that evaluation process? Is there any information you can provide to the Board in terms of the price tag, if

you will, if I can put it that way, for the time involved to carry out that evaluation process?

A. I can't give you an accurate or even an inaccurate number from Canadian files primarily because that subject is under consideration right now by the Treasury Board of Canada in its exercise in looking at cost recovery programs, but I can tell you that in the United States the cost for evaluation.

In Canada there is a nominal fee, and it escapes me right now what it is, but it is of the order I think of $100 or it was $100 until fairly recently.

Q. And that is taxi fare to get the material there?

A. I'm sorry?

Q. That's taxi fare to get the material?

A. Well... In the United States, the registration standard process, which I discussed briefly during the course of my presentation, the process of re-evaluating a pesticide which, for all practical purposes, one might say is very similar to evaluating a new submission, except that there might be much less data to evaluate because it is an older product, that process in the United States has been estimated to cost 2 to 3 PYs and in the order of $100,000 in extramural funding per chemical, and I

can't imagine why the cost would be substantially different in Canada.

So if we were to look for a ballpark figure, I would think it's -- that could be off by 50 per cent, but to give you a sense of magnitude, I think it is somewhere in that order.

Q. All right. So that if we were then to attempt to arrive at an approximation of the cost consequences to the applicant - just to the applicant of an application of this kind - we could take the U.S. figure that you provided to us, convert it to Canadian dollars and we would receive an approximation of what the costs are just up to the time of submission; is that correct?

A. That's right, yes..

Q. And thereafter if any retesting is required, if any new protocols are to be followed, if any duplication tests are to be carried out, those are incremental costs?

A. Yes.

Q. Would you agree with me, Dr. Ritter, based on your experience, that it is not at all unusual for the costs for a pesticide registration applicant to range in Canadian dollars from anywhere to 25- to over $30-million depending upon the nature of the evaluation

process and the materials required to be submitted?

A. I have seen that number used frequently, yes.

Q. And there are cases in fact where the costs are higher?

A. Yes.

THE CHAIRMAN: Ms. Cronk, if I could ask some questions arising out of that.

Dr. Ritter, I take it for this kind of investment on the part of companies that their formulations would be or they would attempt to protect their formulations through some kind of proprietary property registrations of some kind, patent registrations, et cetera?

DR. RITTER: Yes.

THE CHAIRMAN: And, therefore, this data that you are receiving from various outside sources would be confidential to the extent that competitors would not have access to it; is that correct?

DR. RITTER: That's correct.

THE CHAIRMAN: And, therefore, there would be no way of subjecting that data to scrutiny of others other than your department or other regulatory agencies to which this has to be submitted who, I take it, are under an obligation not to divulge information

that would obviate the proprietary confidentiality of some of this information; is that correct?

DR. RITTER: That's correct?

THE CHAIRMAN: And so in this sense there isn't the availability of public scrutiny that you would normally allow data to be subjected to in another context; i.e., if it weren't subject to a proprietary interest in favour of a particular party?

DR. RITTER: It's correct that the laws in Canada and in the United States and in many other jurisdictions prevent or prohibit the release of that information to third parties. I'm not sure that it's necessarily correct that that's unlike the situation in other areas.

THE CHAIRMAN: Well, for instance, as I understand it, correct me if I am wrong, the Alachlor Review Panel sought undertakings from various participants not to divulge any information that would -- like, outside of that process that was not required for that review; is that correct?

DR. RITTER: No, I think you may have been mislead in part. There were undertakings which were required by participants of the Alachlor Review, but insofar as it was a public inquiry, all of the toxicology information, all of the environmental impact

information, all of the evidence which was presented, discussed, cross-examined during the course of those 17 months were a matter of public record.

I would say the only components that were held in-camera and for which those binding agreements were entered into related primarily to formulation chemistry.

THE CHAIRMAN: Okay.

DR. RITTER: And virtually exclusively to that area.

THE CHAIRMAN: And, in your professional opinion, do you feel that any of this proprietary interest consideration in any way inhibits the evaluation of the product?

DR. RITTER: None whatsoever.

THE CHAIRMAN: So you are confident that you are getting everything that you need or your deparment needs in order to effectively evaluate something?

DR. RITTER: Yes. I am truly confident because it is not a process which is being carried on exclusively in Canada and, whereas the data to which you refer may not be subjected -- are prohibited from disclosure to third parties in Canada, there is, as you can well imagine, interaction between various

regulatory agencies, both nationally and internationally.

So although there is not the public consultation, if you like, to which you refer, there are certainly consultations. The Alachlor example which you illustrated with a moment ago, there were extensive consultations that took place between ourselves and the United States Environmental Protection Agency.

THE CHAIRMAN: And that type of consultation between scientists--

DR. RITTER: Yes.

THE CHAIRMAN: --for non-commercial purpose--

DR. RITTER: Yes.

THE CHAIRMAN: --is permissible, I take it?

DR. RITTER: Well, I think I would have to ask my counsel if it's permissible. We do it, and I am not going to offer you a legal opinion as to whether or not it's permissible.

MS. CRONK: I think you usually ask your counsel about that before you give the answer, but that's a small point.

DR. RITTER: Well, I'm not commenting on

whether or not it's lawful, I'm simply saying we do it.

THE CHAIRMAN: Okay. Thank you, Ms. Cronk.

MS. CRONK: You're welcome, sir.

Q. Do I understand with respect to the involvement in this country, however, of various federal agencies, Dr. Ritter, that there is a consultation process, if I can put it that way, inter the various federal agencies concerning a pending application?

DR. RITTER: A. Yes, we meet approximately every six weeks, the departments involved federally in pesticide regulation.

Q. And is the information and data made available to you by the applicant made available to other federal agencies for their consideration as part of the evaluation process?

A. It's actually simpler than that. The data is in essence made available to the Department of Agriculture, so anything that is made available through submission to the Department of Agriculture, the department with statutory authority in Canada, is, if you like, made available to all core departments.

Q. So each then of the agencies that you have depicted on Exhibit 709A has access to the

complete data package, complete submission material put forward by an applicant for registration; is that correct?

A. They can if they so desire. We, for example, will rarely request anything except information relating to human health, but we would have access to fish or environmental or --

Q. If you sought it?

A. That's right.

Q. All right. And am I also correct that other jurisdictions in addition to Canada, just dealing with the pesticide registration context, other jurisdictions apart from Canada protect proprietary information in a way conceptually similar to that done in Canada, the United States for example?

A. The United States does and that's about the only jurisdiction I can comment on.

Q. All right, thank you. Could I ask you to put Exhibit 709 briefly back in front of you, if you would please, Dr. Ritter.

And, again, dealing with cost issues to the applicant in bringing forward a pesticide for consideration for registration, if you could look just at page E, if you would for a moment. That's the page that identifies, as I understand it, a number of the

long-term tests required by your department?

A. Yes.

Q. All right. One of which is chronic feeding tests?

A. Yes.

Q. Chronic studies?

A. Yes.

Q. You have told the Board, as I understood your evidence, that those studies require dietary administration of the subject active ingredient to rats; am I right in that?

A. Yes.

Q. And it is for at least -- was it 90 per cent or 80 per cent of the lifespan of the rat?

A. 90 per cent of the anticipated lifespan of the rat which translates with most strains of rats being used today to no less than 24 months.

Q. All right. So we are looking then at a study requirement that a study continue for at least two years?

A. That's right.

Q. All right. And after that, as I understand it, the pathology is required?

A. More than just the pathology. There is a variety of clinical investigations which go on

after that time and they would include pathology, haematology, biochemistry, urine analysis, organ weights, tissue residue analysis, so on and so forth.

Q. So all of the laboratory analyses then take place after that two-year period?

A. That's correct.

Q. Then there is the process of report writing--

A. That's right.

Q. --compilation and interpretation of the data collected?

A. That's right.

Q. Is it fair to say, Doctor, that just to do one of those studies can take anywhere from approximately four years or more; it can be that long?

A. In our hands we find that the in-life portion typically runs about two years and we tend to look at the reporting time to be about four years from initiation of the study.

I would say that virtually no study is ever reported in less than about four years from the time that it has been initiated.

Q. And that's for one chronic feeding rat study?

A. But many of these studies are going

on concurrently.

Q. All right.

A. But that's for one chronic feeding study, that's correct.

THE CHAIRMAN: Did you say that you analyse after the two-year period?

DR. RITTER: That's correct.

THE CHAIRMAN: You wouldn't analyse ongoing, like as --

DR. RITTER: There are a limited number of parameters that are investigated on an ongoing basis, but because the nature of the study is to determine effects which may be associated with chronic exposure to the chemical, chronic exposure should first take place before those effects are evaluated.

To put it into another context perhaps, the cancer example that I used before, we tend to think of cancer as being primarily a disease of mature onset. It would not be --

MS. CRONK: I'm sorry?

DR. RITTER: A disease of mature onset. It would not be very informative to look for the appearance of tumors in a study at one year, for example, when you would not normally expect these tumors to start appearing until 20 or 22 months into

the study.

Now, there are daily, weekly, depending on the particular protocol, there are regular clinical pathology observations that are made throughout the course of the study, though should those tumors appear much earlier than two years - and that has certainly been the case for a number of compounds - they too would be discovered.

But as a matter of routine, as a matter of protocol, because these studies are designed to assess effects associated with long-term exposure, the objective is, of course, to ensure that long-term exposure has first taken place.

MS. CRONK: Q. Can you estimate for the Board, Dr. Ritter, the approximate costs associated with producing over that four-year period one chronic feeding study?

DR. RITTER: A. $2-million.

Q. Canadian dollars or U.S.?

A. It is roughly $2-million.

Q. Here or there?

A. The numbers always refer to U.S. dollars. That number may vary a little bit depending on whether or not the study is done in-house or the study has been contracted out.

As you can well imagine, studies that are contracted out tend to cost a little bit more, but $2-million again. What I am trying to impart is a sense of an order of magnitude rather than a precise dollar value. It's not a hundred thousand, that's the message I am trying to impart.

MR. MARTEL: Could I ask you a question then? If the feeding period is two years, you are saying that the testing, laboratory testing thereafter takes two more years?

DR. RITTER: Laboratory testing, analysis and report writing, that's correct.

MR. MARTEL: Have you got a shortage of staff or is it just not possible to do it any quicker?

DR. RITTER: Well, let me give you some numbers that may give you a sense of perspective on the study that we are talking about.

A typical cancer study will have three dose groups and a control for each sex. So what you will have is a total of eight dose groups in the study; four for the males, four for the females, each of which will contain at least 50 animals and in many studies may contain more than that. So for the males you will have a total of 200 animals and for the females you will have a total of 200 animals.

In terms of pathology, by way of example, there are approximately 60 organs or tissue systems that are examined on each animal. So if we think of 4- to 500 animals - and I'm not going to endeavour to do the arithmetic in my head - and roughly 60 organ examinations per animal, what does that come out to, 30,000? 30,000 tissue examinations, 30,000 diagnoses that have to be rendered.

We can go through that same kind of a calculation for biochemistry and I think I saw one reference that estimated that there are approximately one million data points in a two-year chronic feeding study.

MR. MARTEL: Okay, thank you.

MS. CRONK: Q. Coming back then to the approximation that you provided concerning the costs of a two-year chronic feeding study, that $2-million figure I should fairly think about as a ballpark figure in American dollars?

DR. RITTER: A. That's right.

Q. All right. And if we could just by way of another example for the Board deal with the issue of cancer studies as you have raised it, how long from start to finish does one of those tests normally take, one of those studies?

A. Cancer studies?

Q. Yes.

A. The in-life portion, if the study is conducted in rats, would be at least 24 months and if conducted in mice is at least 18 months. The actual duration of the study in mice is defined by a different set of parameters, but will usually run no less than 18 months.

Q. Are they required in both species?

A. Yes, they are.

Q. All right. Is that incremental time or can they be undertaken concurrently?

A. Concurrently.

Q. All right. And after that we have again all of the steps that you mentioned in terms of analyses of the data and a consideration of it, evaluation of it, and then the reporting of it?

A. Yes. Less so in terms of laboratory investigations in the mouse study because the mouse studies are generally intended as a tumor counting exercise more or less exclusively.

So that many of the laboratory investigations are restricted to the rat study, but the histopathology is an exercise that both the rat and the mouse study are subjected to.

Q. Are we talking, Dr. Ritter, four years for a study of this kind as well?

A. It's -- again, that's the order of magnitude. It may be three and a half years in the case of a mouse study, but something like that.

Q. All right. And what are the approximate costs to the applicant of conducting a study of that kind?

A. About $1.5-million.

Q. In U.S. dollars?

A. Yes.

Q. Would you agree with me, Dr. Ritter, that taking those factors into consideration, both the time factors of individual studies and the overall time period that is typically experienced by applicants as well as the cost factors, that it is a very serious investment and a long-term investment for a manufacturer to undertake an application for pesticide registration approval in this country under the current system?

A. Yes.

Q. And that that -- am I also correct that that applied equally to those chemicals that currently bear registration status for forestry uses, the same situation applied?

A. By and large. As you can well imagine, the data requirements have changed over the years and through that period of time there have been more and more studies that have been added to the list of required studies.

So depending on what chemical you are referring to and what point in time it may have been registered at, that would have determined the study requirements that were in place at that particular time. So it is a function of when it was registered as to exactly what data would have been required.

Q. And certainly with respect to new products, those are the implications for an applicant; in terms of both time and cost, it is a major long-term investment of both; is it not?

A. Yes. It is the implication for any product that's been registered within the last 8 or 9 or 10 years.

Q. All right. And from today forward--

A. Yes.

Q. --any product that is either in progress as part of a pending application or an intended application or any that might come down the line in the future?

A. Yes.

Q. Would you also agree with me, Dr. Ritter, or are you in a position to agree or disagree that the market in Canada for forestry applications of pesticides is very small, comparatively speaking?

A. Yes.

Q. For example, the market for agricultural usage is much larger indeed?

A. Yes.

Q. And that therefore I suggest, and I would welcome your views, that an application for pesticide registration for forestry uses alone is uneconomic?

A. I am going to prefer not to comment on that. There are many considerations I think that go into the viability of how attractive is the application.

Q. All right. Based on your experience of the applications that you have seen come through your department, have you ever seen an application that was restricted purely to forestry uses?

A. There are such registrations in Canada. Fenitrothion is an example.

Q. All right. And, as a general matter then, taking into account the extent of the market both for forestry uses and agricultural uses, would it be

fair to suggest that it would be rare to see a pesticide registration application restricted to, in the application, a forestry use alone?

A. Yes.

Q. I am suggesting really, not to make it more complicated than it need be, Dr. Ritter, that there is very little incentive, given the market, in dollar terms alone for an application for pesticide registration for forestry uses alone in Canada?

A. I would prefer to say that there is a small market. As to whether or not it's economically attractive, I think there are considerations that go beyond the size of the forest market.

Q. All right, that's fair, Dr. Ritter. The Board has, for example, heard evidence that the -- through I believe Mr. Churcher when he testified, that the manufacturers of madacil have withdrawn their registration of that product because of market circumstances. Are you aware of that?

A. That is what they indicate to me, yes.

Q. I take it there are instances where that has occurred, apart--

A. Yes.

Q. --apart from madacil?

A. There have been instances certainly where that has occurred. I think I can think of one off the top of my head.

Q. All right.

THE CHAIRMAN: Could the Board make this kind of leap, if I might put it that way, that if most pesticide registration -- applications for registration are not just for forestry use, they include agricultural use, that the registration requirements for agricultural use; i.e., where they are sprayed or used with food that is ingested primarily by humans, would be more stringent than just for forestry use where exposure is, at least to humans, is somewhat limited?

DR. RITTER: No, actually that would be incorrect.

THE CHAIRMAN: That would be incorrect?

DR. RITTER: That's right. The data requirements which we have for human health and safety are identical regardless of final application. So that we impose exactly the same toxicology data requirements on a chemical which will be used exclusively in the forestry sector as we would for a chemical that will have wide-spread application to food.

THE CHAIRMAN: Okay. Is that the case in

other jurisdictions as well?

MR. RYDER: No, it's not. The United States, for example, has frequently waived the requirements for some long-term studies and other special studies where it is evident that the chemical will be applied -- will be used strictly in the application to forests.

THE CHAIRMAN: Okay. So that you could draw the conclusion that if it is going to be used for a use that is in addition to forestry purposes that the level of data that you will require, in terms of human health safety, will be at least as good as that required where humans are primarily exposed to the chemical?

DR. RITTER: It will be identical, in fact.

THE CHAIRMAN: In Canada at least?

DR. RITTER: That's right.

THE CHAIRMAN: Okay.

DR. RITTER: With the exception of food residue data specifically, chemical data relating to the actual concentration of residue in the food. But for all of the studies which I have described which do not include food residue data, all of those studies are required for every application regardless of the

intended use.

We tend to look at those studies as telling us something about the intrinsic toxicity of the chemical; whereas we tend to look at the exposure study as telling us about the potential hazard that those intrinsic features may present. So that the toxicology studies per se are a fundamental requirement regardless of use.

THE CHAIRMAN: Thank you.

MS. CRONK: Q. Dr. Ritter, is it fair to say that it is not an easy matter in this country to have a pesticide accepted for and approved for registration?

DR. RITTER: A. I would say that is fair to say.

Q. All right. And that any suggestion that a new pesticide be considered for registration purposes for use in forestry application represents, both in terms of time and cost, a very serious matter both for the manufacturing industry and for those who in the end hope to use the product?

A. Yes.

MR. MARTEL: Can I ask a question? I want to go back, if I could.

If the standards are the same for testing

and the requirements are the same for food as for other usages, in the last several years the provincial Ministry of Agriculture has been doing a great deal to try to encourage farmers to become much more involved in the proper application.

Has the problem been in the farming community - you might not know the answer - that they are not using proper equipment and so on as opposed to the quality of the product they are using? Because farmers have had, according to my information, higher incidence of illnesses and so on. And is that because of the way that they are applying it, mixing it and so on and not the product itself, or overexposure, is it the problem?

DR. RITTER: You have asked many questions, Mr. Martel. I would like to perhaps deal with the one in the middle first.

You said that you have information that suggests that farmers are at unusual risk - I'm paraphrasing what you said - for some risks.

MR. MARTEL: Mm-hmm.

DR. RITTER: But for many risks, particularly a variety of chronic diseases including cancer we know that farmers are at substantially reduced risk.

That information has been published by a number of different sources around the world including our own laboratory which is just in the midst of the largest epidemiology study ever untaken in the world on farmers and the information we have thus far is that there is actually reduced mortality and a reduced incidence of death from all causes of cancer among farmers.

Although the observation that we have made is somewhat more precise because of the number of people involved in our study, it is certainly not the first time that that observation has been made. Farmers are at increased risk from a variety of mechanical injuries. For example, a variety of working- related deaths due to equipment failure, so on and so forth.

But if you are talking specifically about chemical risk, there is a substantial amount of information in the literature that I think might argue the point that you made.

MR. MARTEL: Well, I'm simply going by the number of articles one reads and the effort to get farmers more directly involved in utilization of proper equipment and so on, that it seemed to have lagged behind other parts of society in terms of occupational

health and so on in that form of protection.

DR. RITTER: I think that's correct. I think your second assertion is correct, I think it has lagged behind and I think that's largely because, as you know, farming generally speaking has not been subjected to the kinds of industrial hygience practices and regulations that we are accustomed to in the more industrialized setting.

We do encourage farmers to monumental -- through monumental efforts really to try to reduce their overall exposure to pesticides, but that is not because we necessarily believe that they are an increased risk of cancer, it's because we do believe that it's important to try to reduce their exposure to these chemicals to as low as is practical.

It's inadvisable to have exposure to these chemicals beyond that which is absolutely necessary in the conduct of one's work and if one can reduce that exposure by a fifth or a half or a third, then that is a desirable objective.

MR. MARTEL: Thank you.

MS. CRONK: Q. Dr. Ritter...

THE CHAIRMAN: Sorry to interrupt as we go along but rather than try and save it to the end, it's easier for us to understand as the questions

arise.

MS. CRONK: I appreciate that, sir, and I welcome it. That's fine.

Q. Dr. Ritter, you mentioned some research in your discussion with Mr. Martel that your own laboratory is doing concerning the carcinogenic risk, I take it, of farmers?

DR. RITTER: A. That's correct.

Q. Is that study complete and is the information available?

A. The study is not complete. If I may perhaps, I should just take 30 seconds just to very quickly introduce that study.

The study is what we refer to as the Canadian Farm Operator Mortality Study. It was initiated about 6 or 7 or 8 years and is a cohort study involving an examination of cancer risks among those groups of Canadians that we felt were perhaps at highest risk from exposure to pesticides, and that was the Canadian farm community.

It's a census-based record linkage study which is based on the 1971 census of agriculture and includes all those people whom, for the purpose of taxation, were considered to be farmers in 1971. So that anyone who was farming for a living in 1971 is

included in this study and it thus includes 365,000 people.

Q. Does it address specifically, Dr. Ritter, the carcinogenic risk posed for farmers exposed to chemicals used in farming operations?

A. Yes, it does.

Q. All right.

A. It does not examine -- it does not attempt to examine the relationship between exposure to any given chemical and any outcome, but does examine the relationship between agricultural practices of a variety of types and cancer outcome.

Q. All right. Has there been any interim assessment of the results of that study been prepared yet?

A. Yes. Because of the magnitude of the study we chose to analyse the date on a provincial basis, particularly because cancer data in Canada is gathered on a provincial basis through the provincial cancer registries.

The analysis for the Province of Saskatchewan is in a somewhat advanced stage and preliminary findings from that analysis were presented at the annual convention of the Canadian Public Health Association in June of this year.

Q. All right. Could you provide me through Ms. Murphy with a copy of the interim evaluation or interim assessment of those results?

A. Yes.

Q. Similarly with respect to the results, particular to the Province of Ontario, can you tell me at what stage of progress the evaluation of the results are for our province?

A. Not done.

Q. They are not done?

A. No.

Q. All right. Could you through Ms. Murphy undertake to provide to me if, during the currency of this hearing, a copy of the assessment results for the Province on Ontario on both an interim and a final basis once available?

A. Yes.

Q. Thank you.

MR. MARTEL: Do all provinces have a cancer registry.

DR. RITTER: All provinces have a cancer registry now, yes. To the best of my knowledge.

MR. MARTEL: When did that come in?

DR. RITTER: I can't tell you precisely off the top of my head. There is a national registry

which is maintained in Ottawa and there are provincial cancer registries which form the basis for the national register.

MR. MARTEL: Well, again, I might be wrong, but my understanding was there wasn't one for all the provinces. I could be wrong.

And that one of the problems confronting Ontario has been, in dealing with cancer mortality, that if someone -- let me use a gold miner, no specific label, let me just say a gold miner dies but he dies from a heart condition, but in effect it was as a result of the cancer the heart simply gave out, that in fact they show up as a heart failure and not as dying from cancer.

DR. RITTER: But that is a somewhat different question, I think, than you asked. You are asking about causes of death on death certificates.

MR. MARTEL: Yes. Well, how else would you register them? And that is not showing up on the death certificates. That is the information I have, again, it could be wrong, but...

DR. RITTER: Yeah, that possibility that you are referring to exists in our particular study. This study I should say is done cooperatively between our own laboratory and the Canadian Centre for Disease

Control.

We certainly considered that possibility six or seven years ago when the study was initially undertaken and although I cannot supply you with the detail of the experimental protocol which dealt with that aspect of the study, it is certainly one that was addressed and I know we went to some length and considerable expense for hand verification of death certificates and charts on these patients to ensure that there were not confounding factors of that type.

So I don't expect that it's significant, that it has in any material way influenced the results in our study.

MS. CRONK: Q. Dr. Ritter, you indicated that the study was a cohort study?

DR. RITTER: A. That's right.

Q. That term is going to be relevant to something I wish to discuss with you later. I wonder if you could briefly describe to the Board's what's meant by that term?

A. There are many different kinds of protocols which one can follow in an epidemiology study, but two very popular methods are one that we refer to as a cohort and the other is a case control.

In a cohort investigation one examines

everyone who could potentially be at risk and then essentially looks for the outcome of interest, in this case cancer. The other approach is to deal with case control.

And cohort studies by their nature tend to have a very large number of people involved but may often have a very small number of cases of interest, and that's its strength and both its weakness.

A case control study on the other hand starts with the case of interests and; that is, if you were interested in for example non-Hodgkins lymphoma, you would first extract from files the cases of non-Hodgkins lymphoma and then try to reconstruct exposure events that may have taken place that may have contributed to the onset of the disease.

The weakness of the case control study is that it relies very heavily frequently on memory recall of events that may have taken place over a very long period of time.

Both these studies have their strengths and their weaknesses and, in fact, are often done one after the other consecutively. It is not infrequent to see a cohort study done which may identify a pocket of interest which would subsequently be followed by case control study to confirm what may have been suspected

from the cohort study.

Q. And when we talk about the cancer studies -- I'm sorry, the epidemiological cancer studies that have been done with respect to pesticides, do we often find that those kinds of studies fall into one of two groups, either the type of cohort study you have just described or the case control type of study that you have just described?

A. Yes.

Q. And indeed - and we'll come to -- I have some questions for you about this - but when we look at the state of the current scientific literature on studies of that kind, do we find a discussion of the advantages and disadvantages of those types of studies and which are more reliable?

A. Yes. There is certainly -- I think most publications in that area tend to preface their comments with a discussion of the two designs and why one has been selected over the other. I don't know that one is necessarily preferable, it depends on a given set of circumstances.

As I indicated, they both have weaknesses and strengths. It really depends on what sort of information one has to work with which often determines the kind of study that one must do.

Q. All right. Thank you very much. Could I ask you then, Dr. Ritter, for your comment on something else unrelated to the time implications and the final implications of seeking registration status for a pesticide, and that has to do with some of the evaluations that are made by regulatory authorities.

If, as a result of evaluating a registration application for a pesticide in this country, if the applicable federal agency determined that there was "no effect", or no adverse effect from the product, what in essence does that form of description mean to you; what do you understand that kind of a description to mean?

A. It was without significant biological effect.

Q. All right. And is that a term that is frequently used, for example, by the United States Environmental Protection Agency?

A. Yes.

Q. And what is your understanding of what it means when an agency of that kind in that jurisdiction forms that conclusion and affixes that description to a study?

A. Same as in Canada.

Q. All right. And is that in this

jurisdiction, in your experience, a description or a conclusion frequently drawn or easily drawn? I suppose those two are different.

A. They are very different.

Q. Let me put it to you again.

A. It's frequently drawn, it's never easily drawn.

Q. All right, thank you. I take it you are aware, Dr. Ritter - and we have come to this perhaps a little sooner than I had anticipated, but there is no reason not to deal with it now - I take it that you are aware, and I would ask if this is so, that an issue has arisen in these proceedings regarding the human health effects of pesticides registered for use in forestry in Ontario?

A. Yes.

Q. You're aware of that?

A. Yes.

Q. And given your responsibilities with the Department of Health and Welfare and the nature of the work carried out by that department regarding pesticides, are you generally familiar with the existing scientific literature regarding the human health effects of pesticides authorized for use in forestry in this province?

A. I would say at this moment in time I'm peripherally familiar with the status of those studies.

Q. All right. Have you, during the course of your experience with the department and by virtue of the nature of the evaluation process that the department undertakes, addressed in the past the state of the scientific literature on different pesticide products as they relate to human health effects?

A. Yes.

Q. All right. You are no stranger to reviewing that type of study?

A. No.

Q. All right. Would you agree with me that the current scientific literature does not establish any adverse human health effects from the use of registered pesticides if they are used properly?

A. Yes.

Q. Would you also agree with me, Dr. Ritter, that -- well, perhaps I could ask you this first. Is there any published scientific information available which demonstrates to your satisfaction that there is a significant risk to human health posed by the use of pesticides registered for use in forestry in this province.

A. Not knowing exactly which products are registered for use in forestry in this province, I'm going to say I'm still not aware of it because I'm not aware of any on which we are not actively pursuing action. And I don't think we are actively pursuing action on any pesticides currently issued for use in Ontario forestry.

Q. All right. Can I take from that then, or does it follow from that, that you are not aware of any information - the way I put it to you was - any information which demonstrates to your satisfaction a significant risk to human health posed by pesticides authorized for use in forestry in this country? I put it that way.

A. I want to think about your question very carefully.

Q. Perhaps let me put it to you again, Dr. Ritter. I put it to you in the context specifically of this province, and I understood you to say that you are not familiar with the specific products offhand that were authorized for use in this province.

A. Yes.

Q. But I also understood you to say that you are unaware of any active investigations of any

pesticide products and I took from that that you were implying that if there was information suggesting significant adverse human health effects, there would be activity and there is not?

MS. MURPHY: I think he said he wasn't aware of any action against any product.

MS. CRONK: Fine.

DR. RITTER: That's right. There is interest and ongoing studies on products which may be included in the list of those used in Ontario forestry, such as 2,4-D, but if I understood your question, you are asking of evidence of adverse human effects?

MS. CRONK: Q. I was.

DR. RITTER: A. And I would reiterate then that I am not aware of information that would suggest a serious human adverse effect in association with products registered for use in Ontario forestry to the extent that I am aware of those products used in Ontario forestry.

But I prefaced my documents by saying that there are studies ongoing for any one or a number of these products such as 2,4-D.

Q. All right. Are you aware, Doctor, of any scientific information which demonstrates to your satisfaction that there is a significant risk to human

health effects from the use of the pesticides currently authorized for use by your department?

THE CHAIRMAN: Well, Ms. Cronk, perhaps since this area is somewhat important, I think, in terms of the overall issue before this Board, and since the number of products currently being used in forestry, as I understand it, is not extensive, the actual number is what; 6 or 7 or 8, I forget?

MS. CRONK: In this province?

THE CHAIRMAN: In this province alone.

MS. MURPHY: Well, as we explained earlier, there is a certain number of active ingredients, they are also in different formulations, and my understanding is that while you are right that there are a small -- I mean a small number of both, a small number of active ingredients in the nature of - I forget the number - and then in the number of registrations which, as I recall, came to something between 30 and 40 different registrations, but active ingredients...

THE CHAIRMAN: Well, I was going to suggest that if we took a break that that list of those currently used in Ontario might be put to Dr. Ritter to just briefly look at so that his answers to the questions you are eliciting might be directed without

this caveat.

MS. CRONK: Of more assistance, right.

THE CHAIRMAN: Of the fact that you don't know what is currently used.

MS. CRONK: Could I make this suggestion, Mr. Chairman, that when you take your afternoon break I will confer through Ms. Murphy with the way to expedite that and perhaps in the meantime I can come at it a different way.

THE CHAIRMAN: Okay.

DR. RITTER: I would like to complicate that just a little, if I may. The question that you are asking or the question that you are contemplating asking may infringe on the proprietary nature of the data to which the Chairman referred to a few moments ago.

I'm not sure to what extent I will be able to answer your question, but the only thing I would suggest is that, in your consultation, you might wish to consider including Ms. Prupas at the back of the room who is from the Federal Department of Justice.

MS. CRONK: By all means. All right. May I proceed, Mr. Chairman?

THE CHAIRMAN: Yes.

MS. CRONK: Thank you.

Q. Would you agree with me, Dr. Ritter, that on this general issue; that is, the scientific literature concerning human health effects of pesticides, that depending on the chemical, the scientific literature regarding human health effects is very extensive, the body of literature varies from chemical to chemical?

DR. RITTER: A. When you say the body of scientific literature, are you referring to the shear volume of information available, or are you referring to information freely available in the open literature or both?

Q. For the moment I'm referring to the latter, I'm talking about published scientific literature concerning the human health effects of pesticides and I'm suggesting to you that the extent of the database on that issue varies from product to product. Would you agree?

A. Yes, yes.

Q. All right. And depending on the nature of the product, the database may be extremely extensive or less so; do you agree?

A. Yes.

Q. In the case of 2,4-D for example, it's my understanding that there are literally

thousands of published literature references; is that so?

A. Yes.

Q. All right. And some of the published studies report on specific tests with a narrow focus, focus to a particular test that was carried out and some reflect summary documents or evaluations of other reports on human health effects?

A. Yes.

Q. All right. So that, in essence, in the case of let's take 2,4-D for example, there are in the published scientific literature a number of - could I term them - summary studies which review the state of the scientific knowledge concerning the human health effects of that compound, they are summary types of reports?

A. Yes. In fact, I think one of the best was authored by my own laboratory. We were approached by the World Health Organization several years ago to compile exactly the sort of review that you are referring to and we did at that time on behalf the World Health Organization compile a review of all of the pertinent human health and safety data available in the published literature at that time.

That review I believe is dated about 1986

or so, and at that time included an evaluation of all of the literature available in any language anywhere on earth.

THE CHAIRMAN: And outer space?

DR. RITTER: Well... It's available from the Canadian Public Health Association or through the World Health Organization.

MS. CRONK: Q. All right. That is in fact the type of comprehensive work that is existent in thescientific literature?

A. Yes.

Q. The published literature?

A. Yes.

Q. And that was an effort to identify, summarize and evaluate the existing studies on human health effects of pesticides; was it not?

A. Yes.

Q. And there are others like it - I don't suggest for a moment, Dr. Ritter, that you would feel the same way about them - but there are others like it; is that correct?

A. Yes.

Q. Well, I'm interested in your views particularly, Dr. Ritter, with respect to some of the more recent summary studies, if I can describe them

that way.

Am I right that some of the more recent work has focused particularly on the alleged carcinogenicity of various pesticides?

A. Yes.

Q. Are you familiar with a 1987 report commissioned by the Ontario Ministry of the Environment regarding the carcinogenicity of 2,4-D?

A. Yes.

Q. All right. Dr. Ritter, I'm showing you a report dated March 23, 1987 entitled: Expert Panel Report on Carcinogenicity of 2,4-D bearing the name of the Canadian Centre for Toxicology, Guelph Ontario, Canada. Is that the report to which I just referred?

A. Yes.

Q. And you are familiar with it?

A. Yes.

MS. CRONK: (Handed)

THE CHAIRMAN: Mark that as Exhibit 714.

---EXHIBIT NO. 714: Report entitled: Expert Panel Report on Carcinogenicity of 2,4-D, Canadian Centre for Toxicology Guelph, Ontario, Canada, dated March 23, 1987.

MS. CRONK: I would note for the record, Mr. Chairman, that this report also constitutes the

response to OFIA Interrogatory 28Y on Panel 13 of the MNR evidence.

THE CHAIRMAN: Thank you.

MS. CRONK: Q. Dr. Ritter, I understand with respect to this report that a panel of experts was appointed by the Honourable James Bradley Minister of the Environment to conduct a study and review on the subject of the carcinogenicity of 2,4-D?

DR. RITTER: A. Yes, that's correct.

Q. And the report was prepared, as I understand it, by the Canadian Centre for Toxicology?

A. That's right.

Q. And if we turn to page (ii) do we see there the membership of the experts appointed by the Minister of the Environment to serve on this panel?

A. Yes.

Q. All right. I'm informed, Dr. Ritter, and I would ask for your view, that the individuals identified on this page, there being five in number, are acknowledged authorities in the fields of pharmacology, biostatistics, medicine and toxicology?

A. Yes.

Q. All right. Do you know Dr. I. C. Monroe, one of the individuals named in this list?

A. Very well.

Q. All right. And as I read his name he is the current Director of the Canadian Centre for Toxicology?

A. That's correct.

Q. Did he, before joining the Canadian Centre for Toxicology, have some association with or responsibility with your own department?

A. He was Director General of the Food Directorate.

Q. For Health and Welfare Canada?

A. That's correct.

Q. All right. And is he, in your opinion, an acknowledged expert in toxicology in Canada?

A. Yes.

Q. Do you know Dr. K.S. Crump who is also mentioned in this list of experts?

A. Yes.

Q. And who is he, please?

A. Ken Crump is an expert in biostatistics in the application of statistical principles to the estimation of human risk.

Q. Is he then, in your opinion and based on your knowledge of him, an acknowledged expert in risk assessment and biostatistics?

A. I would say that he is considered by his peers to be among the top seven or eight biostatisticians in the world.

Q. Thank you. Could I ask you to go to the bottom of page 6, if you would. I don't want to leave any inference, Dr. Ritter, that because I haven't asked you about the other individuals that was for a purpose.

I take it, could you give me your opinion, are they acknowledged experts in their respective fields as well?

A. I am less familar with the work of Professor Anders and with the others. Tony Miller is considered by many to be one of Canada's leading cancer epidemiologists and certainly considered to be one of the best in the world.

Bob Squire is currently with the Johns Hopkins University and has had an outstanding reputation in the field of pathology, he makes his living at pathology.

Q. All right. And as I understand it, Professor Miller is in fact Dr. Miller attached to Princess Margaret Hospital in Toronto; is that correct?

A. That's correct. He is an oncologist.

Q. All right. And could I ask you to go

to the bottom of page 6 of the report proper, if you would, please, Dr. Ritter, and do we find there the terms of reference of the expert panel starting at the bottom of page 6?

A. Yes.

Q. And could you indicate to the Board what they were, please?

A. The terms of reference of the expert panel were:

"To assess the validity and health significance of existing experimental and epidemiologic data on the carcinogenicity of 2,4-D and to determine on the basis..."

I am correcting the spelling error here:

"...to determine on the basis of the existing data on carcinogenicity whether any of the existing uses of 2,4-D in Ontario poses significant health risk."

MS. CRONK: Mr. Chairman, I intend to spend some time on this report. If you wish, at your convenience, we can rise now or I could do this first and we could rise then, as you prefer.

THE CHAIRMAN: Well, why don't we take the 20-minute break at this time and then we will go

through until the end of the day.

MS. CRONK: Thank you.

THE CHAIRMAN: Thank you.

---Recess taken at 3:20 p.m.

---On resuming at 3:45 p.m.

THE CHAIRMAN: Thank you. Be seated, please.

MS. CRONK: Thank you, Mr. Chairman.

Q. Dr. Ritter, before we proceed with the Ministry of the Environment commissioned report on 2,4-D, I would like to return to one of the questions I asked you before the break.

Do you have available to you a copy of the ESSA Document that Mr. Kingsbury was testifying about earlier today?

DR. RITTER: A. I do now.

MS. MURPHY: It is Exhibit 604C, I believe.

MS. CRONK: Q. Could I ask you to turn to page 12, if you would, please, Dr. Ritter.

DR. RITTER: A. Yes.

Q. Dr. Ritter, at page 12 we find Table 2 which lists a number of the herbicides, indeed the principal herbicides used in timber management activities in Ontario, and I would ask you to look as

well, perhaps just leaving your finger at that page, over at page 14 to Table 3. Do you have that?

A. Yes.

Q. And that lists the chemical and biological insecticides authorized for use in timber management in Ontario. I take it the names of these chemicals are not new to you?

A. No.

Q. All right. With reference to these chemicals, Dr. Ritter, are you aware of any published scientific literature which demonstrates to your satisfaction a significant human health risk from the use in forestry of these products, assuming used in accordance with the authorizations, label instructions, et cetera?

A. I will just preface my answer by saying, as you can imagine my state of knowledge on the published literature on these chemicals varies somewhat from chemical to chemical. Having said that, no, I'm not aware of any such literature.

Q. All right. In your official capacity as a representative of your department, are you aware of any such scientific literature?

A. No, I'm not.

Q. Thank you. Could we turn then to the

Ministry of the Environment report, Exhibit 714. Before the break I had asked you to outline for the Board, and you did, the terms of reference of the expert panel.

Am I correct, Dr. Ritter, that in the course of conducting its review the expert panel identified and reviewed the available literature dealing with the question of the carcinogenicity of 2,4-D?

A. Yes.

Q. And that literature is discussed and reported upon in this report?

A. Yes.

Q. Am I right as well, Dr. Ritter, that the work of the panel was specific to the question of the carcinogenicity of 2,4-D and possible related effects?

A. Yes.

Q. Could I ask you to go, if you would, please, to the table of contents at page (iii)?

A. Yes.

Q. And just in a summary way for the assistance of the Board, as appears from this table of contents, would I be correct in suggesting that the expert panel considered and reported upon in this

document all of the principal issues related to possible carcinogenicity of 2,4-D?

A. Yes.

Q. And that included both pharmacokinetics and metabolism issues? It included those?

A. Yes.

Q. It included exposure assessment considerations?

A. Yes.

Q. Genotoxicity?

A. Yes.

Q. Pathology?

A. Yes.

Q. Epidemiology?

A. Yes.

Q. Acute and sub-chronic toxicity?

A. Yes.

Q. And then finally the expert panel conducted a risk assessment of 2,4-D?

A. Yes.

Q. The summary and evaluation section of the document begins at page 1 and carries over to page 5. Could we go first to page 5, Dr. Ritter, and I direct your attention to the last sentence which

appears on that page.

And can you tell me, sir, does that sentence reflect the final conclusion of the expert panel with respect to the work it had undertaken?

A. Yes, it does.

Q. And am I correct that the conclusion reached by and reported upon by the panel was that the existing animal and human data are insufficient to support a finding that 2,4-D is a carcinogen, first, that was their conclusion?

A. Yes, it was.

Q. And in consequence of that conclusion the expert panel found insufficient evidence to conclude that existing uses of 2,4-D in Ontario pose a significant human health risk?

A. Yes.

Q. And those uses extended to but were not restricted to forestry uses?

A. That's correct.

Q. Am I also correct that this report was accepted by the Minister of the Ministry of the Environment?

A. To the best of my knowledge, yes.

Q. Now, with respect to item 9 identified in the table of contents, to which I

directed your attention a moment ago, that's the risk assessment--

A. Yes.

Q. --of 2,4-D?

A. Yes.

Q. Sorry, was there something that you needed?

A. No, it was just some information I was getting from my home office which has arrived. The report that you requested, the information which we presented to the Canadian Public Health Association has arrived.

Q. Thank you very much. I will get that at the break then. Thank you.

With reference then to the risk assessment referred to in the table of contents, as I understand it, and I would ask for your confirmation that this is correct and, if it is not, an indication as to where I have gone wrong.

But as I read this document I understand what the expert panel did was to carry out a risk assessment of the theoretical risk to humans from exposure to 2,4-D; is that correct?

A. That's correct, yes.

Q. All right. And am I also correct

that that assessment assumed that 2,4-D was carcinogenic although the panel had concluded, as we have seen from the conclusion, that the data was insufficient to form the view that it was in fact carcinogenic?

A. Yes, that's correct.

THE CHAIRMAN: Ms. Cronk, just going back one second to clarify an earlier answer. You indicated that it was your view that the Minister accepted the conclusions in this report.

DR. RITTER: That's correct.

THE CHAIRMAN: Are you referring to the Ontario Minister of the Environment or the Federal Minister of Agriculture?

DR. RITTER: No, the Ontario Minister of the Environment. The Federal Minister of Agriculture played no part in this document.

THE CHAIRMAN: To your knowledge he is aware of this report?

DR. RITTER: Yes, he is.

THE CHAIRMAN: Are you aware of any views of the Federal Minister on this report? Is your department aware of any official or semi-official position of the federal agencies with respect to this same report?

DR. RITTER: I don't think there is an official or a semi-official position on the work carried out on behalf of the Ontario Ministry of the Environment.

THE CHAIRMAN: There is no unofficial opinion?

MS. CRONK: Well, now, Mr. Chairman...

THE CHAIRMAN: Okay.

DR. RITTER: I don't think I can offer an opinion unofficially as I sit here.

THE CHAIRMAN: Okay, let's go on.

MS. CRONK: Q. On that issue, Dr. Ritter, once this report was published, I take it it came to the knowledge of the Ministry of Agriculture as you have indicated?

DR. RITTER: A. Yes.

Q. All right. Insofar as you are aware, has there been any official commentary positive, negative or otherwise emanating from the Federal Ministry of Agriculture with respect to this document?

A. There have been comments that have been made both during its production and since its publication. By and large I would say that many people have agreed more or less with its review and its conclusions.

Q. All right. Had the Ministry of Agriculture, as the federal ministry ultimately responsible for making registration decisions on 2,4-D, disagreed with or disputed the findings in this report, would you have expected in the normal course of your duties that that disagreement would have come to your attention?

A. Yes.

Q. And has it?

A. No.

Q. Thank you. If we could return then to the risk assessment approach taken by the expert panel. Just to recap, have I correctly understood then that an assumption was made by the expert panel for the purposes of carrying out the risk assessment; namely, that 2,4-D is carcinogenic?

A. Yes.

Q. And they acknowledge that that was a theoretical assumption on their part?

A. Yes.

Q. And could I ask you then, if you would please, to go to the risk assessment section of the document over at page 50.

A. Page 49 I think is where it begins.

Q. Yes, thank you. As you point out at

page 49 and following over to page 51, does that set out the risk assessment analysis conducted by these experts?

A. Yes.

Q. All right. And dealing with the conclusions reached by those experts at page 50, could you outline for the Board what they were, please? I direct your attention to the bottom of page 50.

A. Their conclusions are that the comparisons which they have made suggest on the assumption that even if 2,4-D were a carcinogen the risks to persons exposed occupationally would be considerably less than those for workers exposed to carcinogens at levels recently set by OSHA and less than those from some activities that the general public may regard as safe.

Q. All right. Could I ask you to direct your attention to the first conclusion. What is OSHA?

A. The Occupational Safety and Health Administration of the United States, the organization responsible for administering industrial hygiene standards, if you like, within the United States.

Q. All right. I take it then that the conclusions reached by the panel of experts, even operating under the theoretical assumption that 2,4-D

was a carcinogenic, were that the risks were considerably less for workers exposed to 2,4-D than they were for those exposed to other carcinogens?

A. Yes.

Q. And further that they were in fact -- the risks to which a worker might be exposed from exposure to 2,4-D were less than those which the general public in fact might be exposed to in other activities?

A. Yes.

Q. All right. And then over at Table 8, am I correct that that table sets out the estimated risks under various exposure conditions of 2,4-D as formulated under this risk assessment analysis?

A. Yes.

Q. And dealing with -- the table is in three parts. Could you explain very briefly to the Board what each part of the table signifies?

A. Part 1 of the table is an analysis of hypothetical risks which have been calculated on the basis of the 2,4-D experimental rodent cancer data which in turn has been related to the anticipated exposure levels that various occupational groups may experience during routine use of 2,4-D.

Part 2 of the table refers to a number of

occupational risks that have been recently postulated by OSHA in the United States for chemicals or activities not related to 2,4-D.

And part 3 of the table refers to common risks which most ordinary people in the course of their day-to-day lives might encounter.

Q. All right. Then dealing, if we could, first with part 1 of the table which deals with the risks related to 2,4-D exposure, am I correct that it is to the last column that we should look in that part of the table for the quantification of the risk arrived at by these experts?

A. Yes.

Q. All right. And the quantification of risk is broken down by worker type?

A. Yes.

Q. So, for example, those who are involved in helicopter applications of 2,4-D have risk exposure per million respectively of .6, .3, or .2 per million?

A. Yes.

Q. All right. Can you explain to the Board what that form of quantification means? What I mean by that is, what does .6 per million mean as a risk of carcinogenic effect?

A. Yes. When we project cancer risks for anything, it need not necessarily be with regard to pesticides, we tend to think of that as the excess risk that one might experience from association with that activity.

So that we might say that, in this particular case, that a helicopter mixer/loader would experience an excess risk of developing cancer; that is, a risk in excess of what he might otherwise experience through his normal life which would be something of the order of .6 additional chances per million.

To put that into a more direct comparison, if you think of it as being one in a million, this table suggests more or less that a helicopter mixer/loader might experience a risk approximately one in a million chances greater than what he might have already experienced directly attributable to his activity associated with 2,4-D.

Q. Thank you. And if we then look down the risk quantification column for worker type, would you agree with me that the risks quantified for each worker category are indeed very low expressed as they are in parts per million?

A. Yes.

Q. And, in fact, save only for the category of back sprayers, all the risks are less than one in a million?

A. Yes.

Q. And in the category of back sprayers the risks are respectively 5 and 8 in a million?

A. Yes.

Q. And if we compare those risks of exposure to those experienced by other persons in occupational fields, am I correct that the risk factor, the chances of carcinogenic effect for workers in other fields exposed to other chemicals is considerably higher in each category?

A. You are referring now...

Q. Part 2.

A. You are drawing a comparison to part 2?

Q. Yes.

A. Yes.

Q. All right. And, for example, those whose occupation requires them to be exposed to inorganic arsenic have risks per million of 8,000?

A. Yes. There is another important consideration here which I think I should introduce at this point.

In the case of arsenic and benzene, these are known human carcinogens, there is no speculation as to their outcome.

Q. All right, thank you. So the risk then of exposure to a known carcinogen in the case of benzene, for example, is 3,000 out of a million and 8,000 in the case of inorganic arsenic out of a million?

A. Yes.

Q. Compared to the risks that the panels have concluded apply for exposure to 2,4-D?

A. That's correct.

Q. All right. Can we also agree that those persons who are involved in forestry directly in the application of a pesticide like 2,4-D are, in statistical terms, more likely to experience continued exposure than bystanders who have no association or involvement with forestry applications of pesticides?

A. Yes.

Q. All right. Can I conclude from that then that the risks quantified for workers in forestry, as set out in this table, are the highest one would expect as between the worker -- the occupational worker class and the innocent bystander class?

A. Generally speaking, yes.

Q. All right. And if we compare those risks as quantified by the experts in part 1 for exposure to 2,4-D with the other risks set out in part 3, am I right that what we are really comparing is the risk of cancer that one suffers, if you experience the risk, the risk of cancer that you experience from normal day-to-day activities compared to the risk of cancer presented by exposure to 2,4-D, that's what we are looking at, part 1 versus part 3?

A. Yes.

Q. And the risk of eating peanut products, for example, is 11 out of a million compared to virtually all risks under 1 for exposure to 2,4-D except for the back sprayers category?

A. Yes.

Q. All right. Having a chest x-ray, risk of 1.5 in a million?

A. Yes.

Q. Smoking a cigarette, one cigarette, 0.6?

A. Yes.

Q. And spending a week at an elevation of 3,000 metres in the Rocky Mountains, 0.9?

A. Yes.

Q. All right. Is it fair to conclude

then, Dr. Ritter, based on this risk assessment, that it is clear that the risk of cancer experienced by those likely to be exposed to the use of 2,4-D is, as suggested by the expert panel, considerably less than the risks sustained by persons in other occupational fields and, again, considerably less than the risks experienced by persons in every day activities of the kinds set out in part 3 of the table?

A. Based on the assumptions and the calculations which this panel has used to arrive at their conclusion, I would agree with that conclusion, yes.

Q. The assumption, in the case of 2,4-D, being that it is a carcinogen?

A. That was one of the assumptions but there were several, yes.

Q. All right.

MR. MARTEL: Can we go back for a moment?

MS. CRONK: Yes, sir.

MR. MARTEL: I just want to clarify something. While you asked the question of .6, roughly one person per million and that's based on an exposure, however, of 12 days a year over a 20-year period; is that right?

DR. RITTER: That's correct.

MR. MARTEL: So that if you increased it significantly, let's say workers were exposed four times that amount, 48 days a year over a 20-year period, what's the correlation to that increase to the figure of risk per million?

DR. RITTER: I think the easiest way to answer the question may be to show you the kind of calculation that goes into that exercise. It's not something --

MR. MARTEL: That's what I was afraid of.

DR. RITTER: Well, it's not something that at least I can very readily explain in words.

MS. CRONK: If I could try to assist, Mr. Martel.

MR. MARTEL: Yes.

MS. CRONK: Q. First, it is clear there is a correlation; is there not?

DR. RITTER: A. Yes.

Q. All right. And am I correct that there is no easy rule of thumb to predict the order of magnitude of relationship as exposure goes up? You can't, for example, say multiply by .3, multiply by .4, you actually have to do a mathematical calculation to determine the relationship?

A. That's right. Generally speaking,

the calculation involves the division of the total number of days of exposure per year by the unit exposure, that number is divided by the total anticipated lifespan.

So as the number of days of exposure per year increases, one component of that overall equation changes, but two of the three other components remain the same.

So that there would most certainly be an increase in the risk and it would be proportional to the increase in exposure, but it's not necessarily linear; that is, for a doubling in the number of days of exposure. If the unit exposure is very small, let's say, and one triples the number of days of exposure, one actually hasn't altered the overall exposure very much.

So I don't know if I've made that point clear perhaps, but...

MR. MARTEL: That's why I was scared when you said that you just can't multiply it by four, that we had to get into some complicated way of doing it because it's not that simple.

DR. RITTER: It's not complicated but it's not simple.

MR. MARTEL: Yes. Somewhere inbetween?

DR. RITTER: That's right.

MS. CRONK: Q. It would be, however, inaccurate; would it not, Dr. Ritter, simply to assume that if days of exposure went up by a factor of five, that degree of risk went up by a factor of five. That might not be the case at all?

DR. RITTER: A. In fact I would be very surprised if it was the case.

Q. Exactly. And isn't it also the case that you would require a very substantial increase in the degree of exposure before you had a material increase in the degree of risk?

A. Well, I think I would need to ask you to define material. I think I would prefer to leave my answer as I had it.

The calculation is such that there are three components to it and changing one of them may not necessarily lead to a significant alteration in the overall equation. It really depends which component has changed and by how much.

MR. CRONK: I'm in your hands, Mr. Martel as to whether --

MR. MARTEL: No, that's fine. I didn't think it went up by four times but I just wanted to make sure of that.

DR. RITTER: No, that I am prepared to say is correct, but as to whether or not it changes it materially...

MR. MARTEL: All right, fine. Thank you.

MS. CRONK: Q. All right. Did this --

MRS. KOVEN: Excuse me, Ms. Cronk.

MS. CRONK: Yes.

MRS. KOVEN: I think the point that Mr. Martel was making is a fairly valid one and; that is, when we look at risk assessment we don't assume that those estimations are unchangeable that, in fact, the dose unit will always be the same or that the number of days of exposure wil always be the same.

It's a handy way of looking at a measurement at some point in time, but I think Mr. Martel's point is valid and; that is, in terms of risk assessment we have to look at it as being static and that in fact when applied to a workplace situation there are certainly modifications in those estimates?

DR. RITTER: I would like to expand on that just for a moment, if we may. I think we tend to think of the overall exposure -- if the exposure scenario in itself does not change; that is, if we are talking about a forestry helicopter mixer/loader, and

then two of the three components in that equation are probably fixed, they are probably constants and that is the number of years of anticipated exposure - 20 in this case - and the unit exposure is probably also constant; that is, for every day that that individual works at that occupation his unit exposure will probably be constant.

So that the only variable in that equation in the general case in all likelihood would be the number of days per year at which he works which, in this case, the example uses 12.

The message that I was trying to impart was that because that 12 is only one third of the overall equation and in many cases may represent a relatively small component of the overall equation, changes in that component may not necessarily lead to very large changes in the overall result.

MR. MARTEL: My only concern was, for example, I didn't know how long Mr. Iskra, for example, would be involved annually in preparing. You know, I don't know if he is the guy who moves around the province or across northern Ontario and works in a number of units and I guess that was the only thing I was trying to get at. My concern was in that area.

MS. MURPHY: As I recall, Mr. Iskra did

give some evidence about that and he talked about the various things he did throughout the year. Perhaps we better check the transcript for that passage.

MR. MARTEL: Yes.

THE CHAIRMAN: Dr. Ritter, one last thing. Part of this Table 8, part 3, are those four items mentioned also known as carcinogens to humans.

MR. RITTER: Aflatoxin is, ionizing radiation of the kind one would find in a chest x-ray is, cancer from cosmic radiation is, and smoking most certainly is.

THE CHAIRMAN: Okay.

MS. CRONK: Q. One other point then, Dr. Ritter, dealing perhaps with -- let's take the category of where there is the highest quantification of risk in part 1 of the table for the back sprayers?

DR. RITTER: A. Yeah.

Q. I just want to make sure that I'm reading it correctly. When we look at the number of days of exposure and the years exposed in the case of the back sprayers it's 60 days per year for 10 years?

A. That's correct.

Q. Is this table then quantifying the degree or extent of risk experienced by a back sprayer who has been exposed to 2,4-D for 600 days over a

course of a 10-year period?

A. I don't know. I would have to check the text of this document to see. I don't recall if these -- if the risks expressed here are unit risks or lifetime risks.

Q. All right. Well, perhaps we could both do that over the evening. I suspect that we are both still going be here tomorrow. If you could check that I would be grateful. Thank you.

With respect to the balance of the report, Dr. Ritter - and I don't propose to go through it in detail - is it fair to say, and would you agree with me, that in each section of the report, for example, the section dealing with pharmacokinetics and the metabolism of 2,4-D, or the section dealing with the epidemiology studies that the experts have identified, discussed and commented upon the available scientific published literature concerning those issues in each chapter?

A. Yes.

Q. All right. And they have taken them into account, or at least they so indicate, in reaching the conclusions obtained in this document?

A. Yes.

Q. All right. Do you regard, Dr.

Ritter, this report as an accurate reflection of the state of scientific knowledge concerning the carcinogenicity of 2,4-D as at the time it was written in 1987?

A. Yes.

Q. Yes. Was it, in your view, a comprehensive review?

A. Yes.

Q. Are you aware of any more recent published study, report or review in Canada at either the provincial or the federal level dealing with the carcinogenicity of 2,4-D?

A. No.

Q. This is the most recent then?

A. In Canada, yes.

Q. Yes. Do you share its conclusions?

A. When you say: Do I share its conclusions, I take it you are referring specifically to the last sentence on page 5?

Q. I am.

A. Yes.

Q. Thank you. Now, with respect to similar research or research on the same topic reflected in the published scientific literature in jurisdictions other than Canada, are you familiar with

a recent article published by Bond, et al in Fundamental and Applied Toxicology Concerning the Phenoxy Herbicides and Cancer?

A. Yes.

THE CHAIRMAN: Exhibit 715.

MS. CRONK: (handed)

---EXHIBIT NO. 715: Article entitled: Fundamental and Applied Toxicology Concerning the Phenoxy Herbicides and Cancer published by Bond, et al.

MS. CRONK: Q. As I understand it, Dr. Ritter, and I would ask whether you can confirm this, this article was recently published in the Journal indicated: Fundamental and Applied Toxicology in the United States?

DR. RITTER: A. Yes.

Q. That's a refereed publication; is it not?

A. Yes, it is.

Q. And am I also correct that the authors of this article reviewed the available epidemiology studies regarding the phenoxy herbicides and carcinogenicity?

A. Yes.

Q. And two types of study were at issue, those are the ones that you identified for the Board

earlier, the cohort studies and the case specific studies?

A. That's correct.

Q. Both groups were reviewed?

A. Yes.

Q. And both groups had also been reviewed by the MOE expert panel in preparing their report--

A. Yes.

Q. --on the carcinogenicity of 2,4-D; is that correct?

A. Yes.

Q. And the authors of the Bond article, I suggest - and I would ask for your view as to whether this is correct - reached a conclusion similar to that of the MOE expert panel; namely, that the evidence available in the published scientific literature did not support a conclusion that the phenoxy herbicides presented a carcinogenic hazard to humans?

A. Yes, they did.

Q. All right. Recognizing that the MOE document was particular to 2,4-D, whereas the Bond article that we have just marked applies to the phenoxy herbicides generally?

A. That's correct.

Q. All right. 2,4-D is a phenoxy herbicide?

A. Yes, it is.

Q. Am I saying that correctly?

A. Phenoxy.

Q. Phenoxy, thank you. It is in that category?

A. Yes, it is.

Q. All right. Is glyphosate?

A. No, it's not.

Q. All right. Is - I'm not going to pronounce this one right either - hexazinone.

A. Hexazinone. No, it's not.

Q. Hexazinone, it is not?

A. No.

Q. All right. They are in a different category?

A. Yes.

Q. All right. Based on your review of the article by Bond, et al, do you have any reason to quarrel with the conclusions in the document?

A. I don't have any reasons to quarrel with it, no. There are parts that I may have seen somewhat differently, but I think overall it's a well conducted, scientifically defensible, reputable piece

of work.

Q. Thank you. With respect then specifically to glyphosate, which was not the subject of the MOE document, the Ministry of the Environment document, it was also not the subject matter of the Bond article, because it didn't fall within that category of herbicides; is that correct?

A. That's correct.

Q. All right. Are you aware, Dr. Ritter, of any government sponsored report or study in Canada concerning the alleged carcinogenicity or the prospect of carcinogenicity and human health risks with respect to glyphosate?

A. You said any government sponsored report in Canada?

Q. Yes.

A. No, I'm not.

Q. All right. Are you familiar, Dr. Ritter, with the report prepared in the United States in 1986 for the Department of Natural Resources in the State of Washington by K. Crump, et al regarding the potential human health effects of a number of herbicides including glyphosate?

A. Yes, I am.

Q. All right. And I should say, Dr.

Ritter, as you are aware, but the Board may not be, this report in its entirety is some 200 pages plus.

I'm going to produce to you an extract from that report, but I previously provided you with a copy of the full document and should the Board or any other party wish a copy of the full document, we will make that available. (handed)

THE CHAIRMAN: Very well. This excerpt will be marked Exhibit 716.

---EXHIBIT NO. 716: Excerpt of report entitled: Worst Case Analysis Study on Forest Plantation Herbicide Use published by Department of Natural Resources, State of Washington.

MS. CRONK: Q. This report, Dr. Ritter, is entitled: Worst Case Analysis Study on Forest Plantation Herbicide Use. It was prepared, it seems, by four authors, one of whom was Kenny S. Crump; is that correct?

DR. RITTER: A. That's correct.

Q. Is that the same Mr. Crump of whom you spoke earlier?

A. Yes, it is.

Q. And it appears to have been delivered by a company known as K. S. Crump and Company Inc., is that company, to your knowledge, affiliated or connected with Mr. Crump, Mr. Kenneth Crump?

A. It was a consulting organization which he ran up until about 1987 while he was on faculty at Louisianna State University.

Q. And the report, from its cover page, was prepared for the Forest Land Management Division of the Department of Natural Resources, the State of Washington; is that correct?

A. Yes, it is.

Q. All right. Now, you have some familiarity with the complete document; do you not?

A. Yes, I do.

Q. All right. The extract that we have produced for you, Dr. Ritter, consists of the executive summary and then risk characterization or risk assessment materials relating to glyphosate and 2,4-D from that report. I tell you that simply so you know what materials have been extracted.

A. Yes.

Q. But dealing, if we could for a moment, with the entirety of the report, would you agree with me and can you confirm for the Board that the report represents a comprehensive investigation and consideration of the risks, both in human health terms and in environmental exposure terms, of a number of pesticides including both 2,4-D and glyphosate?

A. Yes.

Q. And do you regard it as a comprehensive detailed document?

A. Yes, I do.

Q. The report in its entirety?

A. Yes.

Q. Dealing if we could then first with the executive summary and page 1 of it, as I understand the nature of the report, its purpose was to analyse - I'm looking at the first page of the executive summary - was to analyse the likelihood and severity of potential health effects in humans from seven herbicides under conditions associated with their aerial application in forests in the State of Washington. And then the authors go on to indicate which seven were considered; 2,4-D, glyphosate and picloram were among them?

A. That's correct.

Q. All right. And it was specific to forestry aerial applications; was it not?

A. That's correct.

Q. All right. And then looking at the next paragraph, paragraph 2 of the executive summary, could you very briefly outline for the Board the approach taken by the authors of the document, the

methodology that they employed in undertaking that analysis as detailed in that paragraph?

A. The paragraph essentially refers to a process which, for all practical purposes, is identical to the one that I described the day before yesterday when I went through the process which we have in place in Canada.

Risk assessment or the evaluation of potential risks essentially involves three steps as I described them the other day. The first involves an evaluation of the intrinsic toxicologic properties of the chemical, that's independent of use and independent of exposure; that is, if a chemical is capable of causing cancer, then it is capable of causing cancer.

The second component of risk estimation is an estimation of the exposure, and we went through that in some detail the other day as well, because whereas the toxicologic properties are unique to the chemical, the extent to which those properties are important is a function of the exposure to that chemical.

In other words, one can have a very potent carcinogen, but if there is no exposure to it there is no risk. Conversely, one can have a chemical in which the effects are relatively trivial, but if

there is very high exposure to a very large population that can translate to very significant risks.

So that the final step in this process is characterization of the risk based on the marriage between the intrinsic toxicologic properties of the chemical and one's anticipated exposure to that chemical.

Q. All right. And in the context of the language that these authors have used to describe the work that they undertook, is it correct that the inherent properties of the chemical are what is meant when they speak of a hazard assessment?

A. That's correct.

Q. All right. And looking at paragraph 2, am I correct that what the study authors did was to undertake really a threefold analysis or three-step analysis, as you have suggested, and that included an exposure assessment, a hazard assessment and risk characterization?

A. Yes, they did.

Q. The last being dependent or flowing from the first two?

A. That's correct.

Q. All right. And if you would look at -- could I direct your attention to the last

paragraph on page 1 of the executive summary and could you outline for the Board, please, the approach taken by the authors in carrying out their risk analysis?

A. Essentially the report is based on the presumption that, in the opinion of the authors, all conditions which were assumed in conducting this analysis were based on the worst possible outcome; that is, in every case of exposure or assessment of toxicology, the benefit of the doubt was always given to the highest possible occurrence.

That is, if there was a range of exposures which occurred in any given study which is typical of any given study, for the purpose of calculation these authors assumed that the highest exposure encountered was the representative exposure.

Q. All right.

A. And that is typically what is meant by worst case.

Q. And they have characterised that as being a worst case analysis; is that correct?

A. That's correct.

Q. So that in any situation where based on the scientific literature it was possible to interpret the study in either a positive or a negative way concerning the degree of risk they, in an effort to

be conservative, adopted always the negative risk interpretation; is that correct?

A. That's correct.

Q. And, similarly, as you suggested, where a study proposed a range of risks some lower than others they always took the highest to ensure conservatism?

A. That's right.

Q. All right. And am I also correct that that concept of conservatism is one that the authors specifically draw to the attention of the readers in the last paragraph of on page 1?

A. Yes, they do.

Q. All right. And they indicate, do they not, that the procedures therefore that they have used tended to be conservative and tended to overestimate - I'm quoting: "...to overestimate the risk to humans." That's what they have indicated?

A. That's correct.

Q. All right. And further that they took that conservative approach leading to such overestimation in all facets of the analyses that they carried out?

A. That's correct.

Q. All right. And could we turn next

then to the -- to page (ii) the portion of the executive summary dealing with hazard assessment.

Am I correct that in considering the hazard inherent in, let's say for example, glyphosate, one of the pesticides that they were considering, the authors looked at a number of potential health effects; namely, cancer; that was one?

A. Yes.

Q. Birth defects or malformations?

A. Yes.

Q. That is the --

A. Teratogenic effects.

Q. Teratogenetic effects.

A. Yes.

Q. Other reproductive effects?

A. Yes.

Q. That includes infertility or miscarriage, the risk of that?

A. Yes.

Q. And then finally what the authors have termed systemic effects?

A. Yes.

Q. And that, as I read the report, refers to such things as the potential for damage to the liver, nausea, headaches, things of that kind?

A. Yes.

Q. All right. And each of those type of health risks was examined with respect to each pesticide under study?

A. Yes.

Q. All right. And that formed the basis for the health assessment?

A. Yes.

Q. And I direct your attention still in the hazard assessment section of the document, if you would, Dr. Ritter, to the second paragraph on page 3 and specifically to the last sentence -- the last two sentences in that paragraph. Perhaps you could just take a moment and read them to yourself, if you would, please?

A. The last two sentences you said?

Q. Yes, in the second paragraph under hazard assessment.

Q. Have you read that, Dr. Ritter?

A. Yes.

Q. Am I correct that in the context of the hazard assessment the authors -- hazard assessments carried out by the authors they are again alerting the reader to the fact that they adopted a conservative approach and, for the purposes of their worst case

analysis, they took in every case the greatest toxic potential from exposure where there was a choice of which exposures to take?

A. That's correct.

Q. All right. And they have indicated in that paragraph; have they not, as I suggested earlier, that where there were two equally plausible conflicting interpretations they took and used, for the purposes of their analysis, that which was most negative to a clean bill of health risk assessment, if I can put it that way, it was the most adverse in terms of risk?

A. That's correct.

Q. All right. They then go on to describe the nature of the risk characterization assessment that they carried out and, looking at the first paragraph of that discussion at the bottom of page (ii), they indicate:

> "For non-carcinogenic effects, systemic, reproductive or teratogenic, a no observable effect level (NOEL) was determined from the experimental data. The NOEL chosen was based upon the most sensitive effect and the most sensitive species."

Stopping there for a moment, is the choice of a NOEL of that kind in itself a conservative judgment as to which to use? Is the fact that it was the most sensitive species and the most sensitive effect relevant to this concept of conservatism, or would that be the traditional approach?

A. I would say that is the convention.

Q. All right. They go on to say that:

"The potential for non-carcinogenic effects in humans was evaluated by calculating margins of safety. These margins of safety are the ratio of the exposure estimates from occupational and environmental scenarios to the estimated NOELs derived from annual toxicity studies."

Now, stopping there for a moment, perhaps I could put this question to you, Mr. Kingsbury, if you have been following the discussion.

Are those the types of margins of safety about which you were asked earlier today I believe by the Chairman.

Sorry, sir, bottom of page (iii) under risk characterization there is a discussion of margins of safety and the question was put to you earlier today

about whether, in assessing carcinogenic or non-carcinogenic effects margins of safety were used, and I believe it was your answer that in some circumstances they are and in others they are not?

MS. MURPHY: No, actually I think my friend might be a bit confused. It was Dr. Ritter that dealt with margins of safety on the first day.

I know there was a question put today to Mr. Kingsbury about the issue of margins of safety and, in fact, as was discussed by -- in response to that question by Dr. Ritter, in fact, today is really a matter that he previously dealt with.

MS. CRONK: Q. I'm aware of that and that is fine. All right. I thought it had been raised today and that is why I was bringing it back to you, Mr. Kingsbury.

MR. KINGSBURY: A. My recollection of what was raised today is are there margins of safety factors applied with respect to the type of environmental studies that I described, and my answer was, no, the rationale in the type of study I was describing is that we are working directly with the organism we are looking for an effect on.

Q. Thank you. So that in the context of this study, Dr. Ritter, when we are talking about

margins of safety, first, we're talking about health effects as distinct from environmental effects of the kind that Mr. Kingsbury was just speaking about earlier today?

DR. RITTER: A. That's correct.

Q. Secondly, we are talking about non-cancer, non-carcinogenic effects; are we not?

A. That's right.

Q. All right. Can you in that context outline for the Board what is involved in the calculation of - I don't mean the mathematics - but what is involved in the concept of using a margin of safety in the concept of this kind of study?

A. The margin of safety approach is the measure of the distance, if you like, between the dose to which you and I might be exposed during typical use of any given product and the dose which did not produce an adverse effect in the test animal.

To give you an example, if we were to conduct study "x" whatever it was looking at end point "y" in that particular study and if we found that that dose level which did not produce the adverse effect in that study was one milligram per kilogram, and if we then went out and measured human exposure to that chemical during typical human application of that

chemical and we found that that exposure was one microgram per kilogram or one 1,000th of a milligram, that calculation would suggest that there is a one thousand fold margin of safety between the no effect level and the human exposure level.

Q. All right. So we are not talking about dose, we're not talking about the amount of the drug?

A. That's correct.

Q. All right. And I direct your attention to the last sentence on page (iii) which reads:

"Depending on the actual data, a margin of safety of 100 or greater may indicate that the human exposure is small as compared to the NOEL and that the risk to humans may be negligible."

Stopping for there for a moment, is that consistent with your understanding of the concept and how it's used?

A. Yes.

Q. And then the authors continue: "The larger the margin of safety (the smaller the estimated human exposure compared to the animal NOEL), the lower

the potential risk to human health."

A. That's correct.

Q. All right.

THE CHAIRMAN: It can be related to dose though, like peripherally related to dose, because if the dosage went up, the point at which you reached an effect might be lower; might it not and, therefore, the margin of safety, because of a higher dose, would be less than if you had a lower dose and a larger gap before there was a known effect?

MR. RITTER: The no effect level in a study will most certainly be driven by the selection of doses in that study.

THE CHAIRMAN: Right.

MR. RITTER: But once the study is complete and the no effect level for the particular end point under investigation has been established, it's a constant.

THE CHAIRMAN: But you would normally expect that with usage of a higher dose the margin of safety would be less than with usage of a --

DR. RITTER: No, because the no effect level is the lowest dose. It's got nothing to do with the top end of the study, only with the bottom end of the study.

If we have a study in which we have three doses; 10 milligram, 50 milligram and 100 milligram and we demonstrate that there are effects at 50 milligram and 100 milligram but not at 10, the no effect level for that particular end point becomes 10 milligram per kilo.

If we then retest that same chemical but instead of going to 100 milligram we go to 500 milligram, as you have suggested, the no effect level for that study remains 10.

THE CHAIRMAN: I see. Okay.

MR. MARTEL: You would have to go back then -- if you wanted to increase the dosage, you would have to, I think you said today, go back and redo the whole thing.

DR. RITTER: Well, if one were unhappy with the no effect level of 10 milligram for whatever reason, because doses are spaced -- for example, on a cancer study they may be spaced logarithmically, there can be quite a bit of distance between doses which, in the final analysis, may not be all that useful; that is, one may have in a cancer study doses that are 10, 100 and 1,000 milligram per kilogram.

Now, if that study by way of example provides a no effect level of a hundred, there is a

tremendous amount of distance between a hundred and thousand milligram and it's entirely possible that the true no effect level falls somewhere between the hundred and the thousand but because those are the doses selected and because there were effects at a thousand and none at a hundred, one must select a hundred as the no effect level.

It frequently happens that one will then go back and repeat that study because one believes that the no effect level is probably much higher than a hundred even though it's lower than thousand, but one simply hasn't selected any doses between those two extremes.

So one might go back and redo that study, but this time instead of going from a hundred to a thousand one might go from a hundred to 250, to 500, to 750, to a thousand and, in that particular case, the new no effect level might well become the 750 milligram dose.

MS. CRONK: Q. With respect to the answers that you have just given to the Board, Dr. Ritter, and as well with the authors of this study have said about margins of safety, would it be appropriate for us in looking at the margins of safety in this report that we are going to come to, to consider it in

terms of a relationship, a relationship between maximum exposure and the NOEL?

DR. RITTER: A. That's correct. That's exactly what it is.

Q. All right. And in that context, it does not relate to dose of the chemical?

A. That's right.

Q. All right. But that it is important to remember that as you vary exposure you will change the margin of safety?

A. That is correct, but you will not change the no effect level in the study.

Q. Exactly. All right. So that the variable that becomes important then is what assumptions are made about the degree of exposure?

A. That's correct.

Q. All right. And am I correct that the authors of this study used maximum exposure assumptions for the purposes of calculating their margins of safety?

A. Yes, they did.

Q. All right. And then the principle that we were addressing last was simply that the larger the margin of safety mathematically the lower the potential risk to human health?

A. That's right.

Q. And, conversely, the lower the margin of safety the greater the degree of risk?

A. That's correct.

Q. All right. And is it also the case that the authors suggest that as the margin of safety approaches the NOEL, the lower the protection, if you will, for humans? I'm saying that badly. As the margin of safety narrows, clearly the more real the theoretical risk becomes?

A. That's correct.

Q. All right. And if we could look at the top of page 4 to the completion of the first paragraph, I direct your attention to the last two sentences and ask for your assistance with respect to them. The authors indicate --

MS. CRONK: This is the third full sentence, Mr. Chairman.

Q. "The actual value of the margin of safety that would be considered to be safe will vary with the quality of the Experimental data from which the NOEL was derived."

Now, stopping there for a moment. Do I understand correctly that the NOEL in each case was

taken from the available scientific literature concerning animal tests, for example?

DR. RITTER: A. That's correct.

Q. Laboratory tests or field tests concerning the results -- toxicity results with respect to animals?

A. That's right.

Q. And where the quality of that data was suspect leading to high results or low results, clearly that will have an effect on the reliability of the margins of safety predicted in the risk assessment?

A. That's correct.

Q. But am I also correct, going back to what the authors had to say about conservatism, that where the NOELs were low or high and there was a choice to be made, they always took the highest?

A. They took the most conservative no effect level.

Q. All right.

A. That's right, but we often -- I'm not sure that we all use the term lowest and highest the same way. They pick the largest number.

Q. So that in this case, when they are pointing out a caution about the quality of the data, it can only have led to an underestimation of the

margin of safety?

A. An overestimation of the risk, that's correct.

Q. Is that not the same thing as --

A. Yes.

Q. Yes, thank you. All right. They go on to indicate that:

"The margins of safety calculated in these analyses are conservative comparisons because they compare generally brief, possibly single-day human exposures to repeated daily exposures generally for weeks or months."

Now, stopping there are for a moment. Can you assist the Board as to what the authors are communicating there regarding conservatism; what is the implication of that statement? What is it that they did that was conservative?

A. With the exception of acute studies which Krump and others reviewed here in this document, all of these studies involve dietary exposure to these chemicals for extended periods of time which might range from a sub-chronic study where exposure might be for 90 days to a chronic or cancer study where exposure might be for 24 months.

They are comparing the results from those rodent studies to anticipated human exposure which, in many instances, may be restricted to one day or, in some instances, may be restricted to several weeks per year. The.

Point that they are trying to make is that there are tremendous differences in the amount of exposure which the animals would have had in the course of these studies when compared to the amount of exposure that one might anticipate humans would have during the use of this chemical.

The implication is that there tends to be built in an additional safety factor because of that.

Q. All right. By additional safety factor, does that in effect mean yet again an overestimation of the degree of risk for humans when you do that kind of comparison?

A. Well, without going into a long mathematical debate as to exactly what the implications of those assumptions are, generally speaking, I would agree with your statement, yes.

Q. All right. It was yet again a conservative approach to take?

A. Yes.

Q. All right. And then finally with

respect to this page of the executive summary, for the assessments that they did of cancer risks from various pesticides, they indicate in the next paragraph that:

> "Cancer risk was assumed to be linearly related to dose as is assumed in the conservative approaches to estimating risk generally used by regulatory agencies."

That on its face, at least to me, appears to be complicated. Does it simply mean, Dr. Ritter, that the larger the dose the larger the cancer risk?

A. No.

Q. Thank you. I'm glad I checked. What is it that the authors are --

A. There are two contemporary approaches to modelling risk to suspect carcinogens. One presumes that there is a level of exposure to a cancer-causing agent which may be safe; that is, that one can achieve a level of exposure which is so low that it constitutes no risk at all.

To put it another way, that school of thought argues that there is a concept of a no observed effect level or a NOEL which is applicable to cancer-causing agents. I should say that that is not the most popular view in the world.

The second school of thought argues that there is no level of risk to a carcinogen for which there is not some attendant level of risk; that is, every level of exposure to a carcinogen has some level of risk associated with it.

What Krump refers to here is the linearized approach and, again, without going into a long complicated mathematical presentation as to what exactly that means, what it does imply is that at relatively low doses that humans experience compared to the relatively high doses used in these experimental studies, there will be a linear relationship between exposure and risk; one to one relationship between exposure and risk.

So that for every level of exposure one can mathematically derive the attendant level of risk. That is by far and away the more conservative approach because it makes the assumption that there is no safe level per se of a carcinogen. That's the approach which Krump has taken in the calculation over here.

Q. And they applied that approach; did they not, to herbicides for which -- even to herbicides for which there was no carcinogenic potential?

A. That's correct.

Q. All right. So even where there was

no evidence in the scientific literature to suggest carcinogenic effect, they took that approach and assumed that there was no level of exposure to that herbicide that was completely safe?

A. That's correct.

Q. All right. You would agree with me that that is an extremely conservative approach for the purposes of risk assessment?

A. No, I don't think I would agree with you that's an extremely conservative approach. I think I would say it's one of two approaches which is commonly practised in the world. It is by far and away the more conservative of the two.

Q. All right. And then --

THE CHAIRMAN: Excuse me a second.

MS. CRONK: Certainly.

THE CHAIRMAN: If you assume for a known chemical that there is a carcinogenic property, even though there is no imperical study that confirms that, what kind of number do you use for the assumption?

DR. RITTER: I'm trying desperately to avoid giving you a mathematical presentation, but I think we are fast approaching that moment.

One plots the data which one has in a dose response relationship, there are then

computer-assisted mathematical models that will extrapolate that data to a region of the curve for which there is no data, and at that so-called low dose region the relationship becomes -- it's postulated that the relationship becomes linear.

The postulate is based on evidence which accommodates the biology of cancer response; that is, the assumption of a linear dose response relationship is, in itself, biologically the most conservative that one could make.

One could then extrapolate, as I say, through this low dose region for which one actually does not have data and ultimately generate an exposure risk relationship based on the data which one did have.

THE CHAIRMAN: Well, is that the same as saying, in a very simplistic fashion, you can take any type of chemical and mathematically postulate enough of a dose that it will cause something at some point in time for whatever type of effect you are trying to look at?

DR. RITTER: Not quite. What it really says is, assume that the data that you have implies a carcinogenic response.

THE CHAIRMAN: Yes, but we are assuming that the data you have does not. Well, you're not

assuming that it does not, you're assuming that it does, but you have no imperical evidence that it does?

DR. RITTER: That's correct. What you're really doing is you're speculating on the residual response which you have been unable to measure.

THE CHAIRMAN: So why theoretically can't you theoretically assume that could you measure right up to infinity you still won't get a response, there is no effect.

DR. RITTER: Well, you could assume that but that simply would not be the more conservative approach. The more conservative approach is that there will be an effect and that it will be present at all levels of exposure.

If one makes that assumption, the one that I've just suggested, and then one attaches to that a particular type of calculation which Krump describes at some length in this paper, the linearized multi-stage approach, one has effectively built in two of the most conservative approaches possible for cancer risk assessment; that is, one -- using these two approaches one is likely to overestimate cancer risk almost in every case, but it's very unlikely to ever underestimate the risk.

MS. CRONK: Q. And in fact, Dr. Ritter,

isn't that one of the reasons that it's done?

DR. RITTER: A. That's precisely why it's done. The imperative within public health agencies is to protect public health. So if there is an error to be made, we will make it on the side of safety and these calculations are predicated on that principle.

There are certainly less conservative approaches that one can take, both in terms of the model and in terms of the mathematics, but it's not the approach that we practise in Canada.

THE CHAIRMAN: Okay. Let's go one step further. If you did that, made the theoretical approach or took the theoretical approach, I presume that the risk assessment would be so low as a result of that that it wouldn't be a concern?

DR. RITTER: That's correct.

THE CHAIRMAN: Because if the risk was high enough to be a concern you would have had data?

DR. RITTER: That's right.

THE CHAIRMAN: Is that fair?

DR. RITTER: That's right.

MS. CRONK: Q. It also follows; does it not, that taking -- utilizing that approach it permits quantification in the risk assessment that would

otherwise not be possible?

DR. RITTER: A. It would be possible by other models and there are other models--

Q. I understand.

A. --that will generate data as well.

Q. But if you did not make the assumption of risk, notwithstanding the absence of imperical evidence to support that, it would not be possible to reach any quantification assuming that you were wrong?

A. That's correct. If one reads the title of this, if one reads the title of this document - I shouldn't say the title - but if one goes through the initial executive summary, what Krump was asked to do here was to assess, among other things, cancer risk.

Now, unless he makes the assumption that these chemicals are carcinogens it would be very difficult for him to assess cancer risk. So he makes the assumption that they are carcinogens, constructs those response relationships based on the data he has, then applies a linearized multi-stage model to the assessment of that data and, ultimately, generates a risk estimate based on those two assumptions.

Q. And, in so doing, can we agree that

the process which must be utilized involves sophisticated modelling and sophisticated mathematics in order to attempt that quantification exercise?

A. Yes.

THE CHAIRMAN: Just to get it straight in my head, I hate to belabour this, but if you have no data and you are going to do a theoretical study like this, then is it not true that whatever the mathematics works out to, the risk will not be considered high enough to concern anybody, because if it were high enough to be of concern, it would have had to have been predicated on some actual data?

Does that make sense?

DR. RITTER: I think I understand your question, but I would like to think about it for a moment before I can agree if it makes sense.

THE CHAIRMAN: And you must assume that this is coming from somebody who knows nothing about any of this.

DR. RITTER: Mm-hmm.

THE CHAIRMAN: In a scientific way.

MS. CRONK: Would it be appropriate, Mr. Chairman, to let the witness consider that over the evening?

THE CHAIRMAN: Sure.

DR. RITTER: Actually I think I can answer it now. I don't think that is correct, because if you were to go through the Ontario assessment, which we referred to a moment ago, Exhibit 714, the risks which were expressed in there are based on exactly these assumptions because, in fact, Kenny Krump did them on behalf of the Ontario Task Force, and indeed many of the risks fall within a range which some may consider to be unacceptable. So that I'm not sure that what you have suggested need necessarily be true.

What this is really doing is it's saying that these studies may not be capable of expressing all of the effects that are associated with exposure; that is, that there may be some residual effects which, because of either limited group sizes or for some other biological principle, have not expressed themselves within the restraints of these studies. And among other things, these models attempt to express that residual risk even though it may not necessarily have been imperically observed.

So that it's possible that one could postulate a risk which might be considered unacceptable even though it's not necessarily based on the imperical data.

In the interest of completeness, I should

say that that approach has been criticized by many because it's really the derivation of a risk based on absolutely no data whatsoever.

THE CHAIRMAN: And you can't prove it one way or the other?

DR. RITTER: Well, the data in fact tells you that there's nothing there; the mathematical calculation tells you there is something there. We have difficulty when the model argues the observation.

The other way around we can accomodate it much more easily, but I must say it's difficult to argue convincingly that the model is right and the data set in wrong.

MS. CRONK: Q. In defense or further defense of the approach, the primary defense being the necessity to embark upon a quantified risk assessment; are we agreed so far?

DR. RITTER: A. Yes.

Q. The second being the conservatism in the approach; does it not, to put it perhaps simply in layman's terms, cover off the possibility that there is some as yet undiscovered carcinogenic potential to a particular chemical which should be considered?

A. That's why it's done and in the Ontario Task Force Report that's exactly the point that

was made.

The point that was made in the preamble was that because there was some controversy surrounding the 2,4-D experimental data at the time that this work was underway, the Ontario study assumed that it would turn out to be positive, that what was equivocal at the time of their review would ultimately become unequivocal and that it would be regarded as a carcinogen, and it was based on that assumption that they proceeded.

Clearly if they assumed or if Krump in this case assumed that these chemicals were not carcinogens, then they would not pose a cancer risk and the calculation would become redundant.

Q. And in the case of glyphosate, for example, in this report that assumption becomes quite material; does it not? They have assumed, as the authors indicate, despite the absence of any imperical data in the scientific literature to support it, the carcinogenic effect from that chemical?

A. That's correct.

Q. All right.

MS. CRONK: Mr. Chairman, I am content to continue or to rise. I clearly won't finish tonight.

THE CHAIRMAN: Well, I think if you won't

finish tonight we might as well go over until tomorrow. There is, I think, a lot of data for everyone to absorb.

MS. CRONK: Yes, thank you.

THE CHAIRMAN: Very well.

Ladies and gentlemen, before we rise for this evening, I feel somewhat embarrassed but I am going to have to put on the record an error which I discovered during the break when I glanced at one of the transcripts.

I happened to glance at transcript No. 112 and noticed that the Style of Cause used is the Style of Cause used in connection with the funding panel, refers to an Order-in-Council and a funding program. I am now advised that this Style of Cause has been used in every single one of the transcripts, going back to transcript No. 1.

Obviously, this Board derives its jurisdiction upon a referral from the Minister not an Order-in-Council with respect to the funding program, and we have advised the court reporters of this and requested that all future transcripts be corrected and we will send out an errata to any depositories that have received the transcripts making that correction.

I am further advised that the

Order-in-Council number given in transcript 112 refers to the first Order-in-Council with respect to the funding program and, as we are all aware, there have been two Orders-in-Council, a subsequent one.

So subsequent to the enactment of a second Order-in-Council, that Order-in-Council number for the funding panel correctly referring to the funding panel transcripts should also be corrected.

So with that, I hope that will clarify it. Certainly it should not be misinterpreted that these transcripts that we are receiving are the transcripts of the funding panel; they are not.

We apologize for this, but it is just one of these things that somehow seem to slip everybody's notice.

Tomorrow we will commence at 8:30 and rise at one or 1:30 in the normal course.

Thank you.

---Whereupon the hearing adjourned at 5:00 p.m., to be reconvened on Friday, August 11th, 1989, commencing at 8:30 a.m.